Supreme Court, U.S.
FILED

No. 03-____

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IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether an interim settlement of patent infringement litigation, in which the alleged infringer, for consideration, agrees to keep its product off the market until the claim of infringement is resolved, constitutes a *per se* violation of the Sherman Antitrust Act, irrespective of the validity of the claim of infringement or the reasonableness of the interim settlement.

PARTIES TO THE PROCEEDING

In addition to the parties named in the caption, the following parties appeared below but are believed to have no remaining interest in the outcome of the petition:

Adverse to Andrx Pharmaceuticals, Inc.

Charles Zuccarini,
Joseph D'Esposito,
Shirlean Glover,
Larry S. Sizemore,
Albert Eirich,
Eugenia Wynne Sams,
Aetna, Inc.,
Cobalt Corporation,
Duane Reade, Inc., and
Louisiana Wholesale Drug Company

Not Adverse to Andrx Pharmaceuticals, Inc.

Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals Inc.)

CORPORATE DISCLOSURE STATEMENT

Petitioner Andrx Pharmaceuticals, Inc. is a wholly-owned subsidiary of Andrx Corporation. Andrx Corporation is a publicly traded company.

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STATEMENT OF JURISDICTION

The court of appeals' judgment was entered on June 13, 2003. Pet. App. 1a. A timely petition for rehearing was denied on July 24, 2003. Pet. App. 86a-87a. On October 6, 2003, Justice Stevens extended the time in which to file a petition for a writ of certiorari to December 5, 2003. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Portions of 35 U.S.C. §§ 154, 261, 271, 282, 284, Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and portions of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Act) are reproduced at Pet. App. 88a-96a.

STATEMENT OF THE CASE

1. This case concerns an acknowledged split between the Sixth and Eleventh Circuits in two indistinguishable cases addressing the appropriate interplay between the patent and antitrust laws in the ever-recurring context of the settlement of patent infringement litigation. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *reh'g denied* (6th Cir. 2003) (Pet. App. 1a) *with Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) (Pet. App. 115a).

Petitioner Andrx Pharmaceuticals, Inc. (Andrx) is a Florida-based generic pharmaceutical company that was sued by a brand pharmaceutical company for seeking to sell a generic version of a brand product, Cardizem CD, in

violation of the brand company's patent rights. When the brand threatened to obtain a preliminary injunction to prevent Andrx from selling generic Cardizem CD, Andrx settled the threatened motion by agreeing to preserve the status quo until the infringement litigation was resolved. Andrx also received payments *pendente lite* and future licensing rights from the brand company. The Sixth Circuit held that this agreement was a *per se* violation of the federal antitrust laws. The Sixth Circuit refused to consider whether the interim settlement was in fact less exclusionary than the lawful exclusionary effect of the patent or indeed whether any anticompetitive effects existed. Pet. App. 17a-21a.

In an indistinguishable case filed by some of the same lawyers and plaintiffs that brought this case, the Eleventh Circuit reached the opposite conclusion on the same issue. Abbott Laboratories sued two generic drug companies for violating its patent rights in connection with the brand drug Hytrin. Abbott obtained agreements to maintain the status quo in exchange for payments and future licenses. The Eleventh Circuit explicitly disagreed with the Sixth Circuit and held that such agreements are lawful and immune from both *per se* and rule of reason scrutiny to the extent they restrain competition to no greater degree than a court might in enforcing the patent. Pet. App. 145a-147a & n.27.

2. This circuit split arose in the context of the patent system's protection of brand-name pharmaceutical products against competition by copycat or generic drugs. The discovery of new drug therapies is dependent on research and development investments undertaken by brand-name pharmaceutical companies. *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433, 435 (1986). These "innovator" companies protect those investments by patenting their inventions. A government-issued patent vests the patent holder with a statutory "right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. §

154(a)(1). The patentee is also legally authorized to enter into agreements with others (that, but for the patent grant, would be its competitors) dividing the United States into territories in which each may exclusively market the patented product. 35 U.S.C. § 261.

Before marketing a patented drug, brand manufacturers must file a New Drug Application (NDA) and secure approval from the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). The safety and efficacy requirements of that process are so demanding that more than a decade may elapse between the innovator's first synthesis of the drug and its generation of revenues. *See* James J. Wheaton, *Generic Competition and Pharmaceutical Innovation*, 35 Cath. U. L. Rev. 433, 448-49 (1986).

Manufacturers seeking to market a generic drug (one that is "bioequivalent" to a drug already approved by the FDA) may file an **abbreviated** new drug application (ANDA) to demonstrate that the biological effect of the generic version is identical to that of the brand product, and rely on safety and efficacy studies submitted by the brand company in the NDA. 21 U.S.C. § 355(j)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Because generic companies do not incur all the drug development costs, generic drugs are generally cheaper than their brand-name "pioneer" counterparts. *See United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 & n.1 (1983).

The Hatch-Waxman Act, which created the ANDA mechanism, is designed to protect innovator drug companies' patent rights. *See Eli Lilly*, 496 U.S. at 675-77. To that end, it requires that the ANDA contain a "certification" concerning any unexpired patents covering the brand product. 21 U.S.C. § 355(j)(2)(A)(vii). In a "Paragraph IV" certification, the type of certification relevant here, the ANDA applicant contends that its generic drug will not infringe the patents or that the patents are invalid and unenforceable. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the

brand company sues the Paragraph IV ANDA applicant for patent infringement within 45 days of the certification notice, the FDA will be barred from granting final approval to the ANDA (even if it otherwise satisfies FDA requirements) for 30 months or until the patent infringement issue is resolved, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2).

FDA approval of a generic drug provides no license to market the product in violation of the brand's valid patents. Indeed, because each sale of the generic product replaces a sale of a more expensive pioneer drug, "a generic applicant's potential liability for lost profits on the brand-name drug usually will vastly exceed its own potential profits after market entry" even before trebling. FTC, *Generic Drug Entry Prior to Patent Expiration*, viii (July 2002) (at www.ftc.gov/os/2002/07/genericdrugstudy.pdf) [hereinafter *FTC Generic Entry Study*]; *see also Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1560-61 (Fed. Cir. 1983); 35 U.S.C. § 284. Given that exposure, the FDA expects "prudent" applicants to wait until the litigation is resolved before marketing and maintains that such prudence "serves the public interest." FDA Proposed Rules: ANDA Regulations, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989); *see FTC Generic Entry Study* at 22-23 (generics do not launch at risk).

3. In 1995, Andrx filed an ANDA seeking permission to market a generic form of Cardizem CD. Cardizem CD was at that time being marketed by Hoechst Marion Roussel, Inc. (HMR), now known as Aventis Pharmaceuticals Inc., which held patents that it claimed covered generic versions of Cardizem CD. These patents are presumed valid. 35 U.S.C. § 282. Andrx submitted a Paragraph IV certification with respect to those patents. In 1996, HMR sued Andrx for patent infringement in the United States District Court for the Southern District of Florida and thereby triggered the 30-month statutory stay of FDA approval. Pet. App. 6a-7a, 97a.

HMR and Andrx both filed potentially dispositive motions, but the patent court issued no rulings and ignored the parties' repeated requests to move the case. *See* Docket Sheet in *Hoechst Marion Roussel, Inc. v. Andrx Pharm., Inc.*, 96 Civ. 06121 (S.D. Fla.). When it appeared that the 30-month stay might expire before the court issued any decision, HMR informed Andrx that it would seek a preliminary injunction to restrain Andrx from marketing generic Cardizem CD upon the stay's expiration. Pet. App. 98a.

Pursuant to their statutory obligations to "cooperate" to expedite the litigation (21 U.S.C. § 355(j)(5)(B)(iii)(III)), HMR and Andrx settled HMR's threatened preliminary injunction through the stipulation and agreement (Stipulation) that is the subject of this case. Pet. App. 97a. HMR agreed not to seek a preliminary injunction, and Andrx agreed to maintain the status quo by not marketing a generic version of Cardizem CD while the patent infringement litigation was pending. HMR also agreed that, if the patent litigation remained unresolved after 18 months or if Andrx lost the patent litigation, Andrx would be entitled to sell its product through a license more than 11 years before the patent's expiration. Pet. App. 99a-100a.

HMR agreed that, if Andrx ultimately prevailed in the patent litigation, it would pay Andrx $100 million for each year that the litigation lasted after Andrx received FDA approval, *i.e.*, a stipulated portion of profits Andrx might have earned had the court hearing the patent case addressed that litigation promptly. In the interim, HMR agreed to pay Andrx $10 million per quarter year until the litigation was resolved; those payments were to be credited against the sum due to Andrx if it prevailed and were to be used to purchase the license if Andrx lost. Pet. App. 100a-102a.

Andrx obtained additional procompetitive concessions under the Stipulation, which increased its ability to ultimately launch a generic version of Cardizem CD. For example, the Stipulation prohibited HMR from amending its labeling

without notice to Andrx (Pet. App. 100a), a tactic brand manufacturers sometimes use to delay FDA approval of generics by forcing generic manufacturers to amend their ANDAs to conform to the new labeling. *See, e.g.*, Naomi Aoki, *Drugmakers Poised for Battle Brand Name Firms Up Stakes In Face of Generic Competition*, Boston Globe, November 26, 2001, at D1. Similarly, the Stipulation defined Andrx's product broadly, so that Andrx would be free to modify its generic version of Cardizem CD without having HMR claim that every modification triggered a new 30-month stay. *See* Pet. App. 110a. Consistent with its desire to market a generic product as soon as prudently possible, Andrx agreed to prosecute its ANDA, thereby assuring HMR a definitive resolution of the patent issues and hastening generic entry. Pet. App. 99a.

The Stipulation avoided a prolonged satellite dispute concerning a preliminary injunction. Nonetheless, the patent court never took action on the pending dispositive motions and did not move the case even during the many months after the Stipulation was publicly disclosed and the statutory stay remained in effect. Andrx continued to defend the litigation. Spending millions of dollars, it reformulated its generic product to attempt to avoid the HMR patent claims. HMR and Andrx then entered into a final settlement of the patent litigation that prohibited Andrx from selling its original formulation but enabled Andrx to sell its non-infringing reformulation with HMR's covenant not to sue. Upon receiving FDA approval of that reformulated product in 1999, Andrx entered the market. Pet. App. 9a-10a.

4. In March 2000, the Federal Trade Commission (FTC) issued an administrative complaint against Andrx, alleging that the Stipulation delayed Andrx's market entry by eleven months. After an exhaustive investigation, the FTC, in April 2001, settled the matter, stating publicly:

> Based on the FTC's investigation, **it does not appear that there was any delay in the entry**

> **into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.**

FTC, *Hoechst Marion Roussel, Inc., et al.: Analysis to Aid Public Comment*, 66 Fed. Reg. 18636, 18638 (April 10, 2001) (emphasis added).

5. During the pendency of the FTC investigation, various putative classes of consumers and direct purchasers, as well as individual direct purchasers (the Plaintiffs), filed private actions alleging that the Stipulation violated the antitrust laws. The private actions were consolidated for multidistrict proceedings in the United States District Court for the Eastern District of Michigan. On Plaintiffs' motion for partial summary judgment, the district court declared the Stipulation *per se* illegal. The United States Court of Appeals for the Sixth Circuit granted leave to appeal the issue on interlocutory review pursuant to 28 U.S.C. § 1292(b). Pet. App. 83a-85a. The Sixth Circuit agreed with the district court that the Stipulation is *per se* illegal. Pet. App. 4a.

REASONS FOR GRANTING THE PETITION

This Court should grant certiorari to resolve the stark split between decisions of the Sixth and Eleventh Circuits regarding the antitrust liability that may attach to patent infringement settlements. In both cases, a patent holder sued an alleged infringer and sought injunctive relief. In both cases, the patentee and the alleged infringer reached a temporary settlement in which the alleged infringer agreed not to enter the market until the infringement issue was resolved. In both, the alleged infringer received consideration. The Sixth Circuit held that the agreement in this case (the Stipulation) was *per se* unlawful. It declared that the absence of anticompetitive effects and presence of procompetitive benefits were "irrelevant," and it refused to

consider whether the Stipulation was a reasonable settlement of a bona fide infringement claim and whether, in the absence of the Stipulation, the patentee would be legally entitled to exclude the infringer from the market. On what Plaintiffs correctly characterize as "identical facts," the Eleventh Circuit squarely rejected the assertion that such an agreement is *per se* unlawful. To the contrary, the Eleventh Circuit held that such agreements are *per se lawful* to the extent that they achieve no more than the patentee might have otherwise obtained through a court judgment.

The issue dividing the Sixth and Eleventh Circuits is certain to recur. Other pending antitrust challenges to patent infringement settlements have already reached the lower courts and one is presently being appealed to the Second Circuit. Moreover, especially in view of the conflict in the circuits, parties to intellectual property disputes need immediate guidance regarding whether antitrust liability may attach to their settlements because it is common for intellectual property disputes to be settled by agreements in which the infringer receives consideration in exchange for a promise to withhold its product from the market. The need for guidance is particularly acute because this Court has not examined the antitrust implications of any patent infringement settlement in over 40 years. *See United States v. Singer Mfg. Co.*, 374 U.S. 174, 190 (1963) (analyzing facts in detail before concluding that "settlement" was a sham); *see also* H. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 Geo. Mason L. Rev. 359, 368 (2002).

The decision below implicates fundamental antitrust principles and seriously erodes the value of intellectual property. The Sixth Circuit failed to follow decades of Supreme Court jurisprudence concerning when *per se* condemnation is appropriate. Moreover, were *per se* condemnation appropriate under this Court's precedents,

then, contrary to the patent law's constitutionally-based guarantee, patent holders would have no right to exclude infringers; they would merely have the right to *try* to exclude them by filing lawsuits. If the settlement of an issue can be condemned as *per se* unlawful where litigating it would foreclose competition even further, competition policy will be seriously undermined. This Court should resolve the circuit split and hold that embroiling federal patent courts in every patent settlement is not necessary to upholding them and that i) the rule of reason governs agreements, such as the Stipulation, in which an alleged infringer promises to abide by an intellectual property owner's demand for injunctive relief, and ii) settlements that go no further than what the patentee could have secured in litigation are immune from subsequent antitrust challenges.

I. This Court Should Grant Certiorari To Resolve the Conflict Between the Sixth and Eleventh Circuits

As the Plaintiffs in this case have themselves recognized, there is a split in the circuits regarding whether an alleged patent infringer may agree to remain out of the market pending patent litigation in exchange for consideration from the patentee. *See Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 1-2 (11th Cir. Oct. 6, 2003) (arguing for Eleventh Circuit *en banc* review in light of the fact that such an agreement "has been expressly condemned, on **identical** facts, as *per se* unlawful by the Court of Appeals for the Sixth Circuit") (emphasis added).[1] The Sixth Circuit, in this case, and the Eleventh Circuit, in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) (Pet. App. 115a), reached opposite conclusions on identical questions arising from indistinguishable facts.

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[1] With one exception, the Plaintiffs in this case are also appellees in the Eleventh Circuit litigation.

In both cases, generic manufacturers agreed to keep any bioequivalent product off the market until the patent litigation was resolved or a future license right was triggered. Pet. App. 8a, 124a-125a. Both decisions arose from multidistrict class actions. *In re Cardizem CD Antitrust Litig.*, 1999 U.S. Dist. LEXIS 9285 (J.P.M.L. 1999); *In re Terazosin Hydrochloride Antitrust Litig.*, 1999 U.S. Dist. LEXIS 19640 (J.P.M.L. 1999). Both cases involved consideration given by a patent holder to an alleged infringer, sometimes mischaracterized as "reverse" or "exit" payments. (In *Cardizem*, HMR paid Andrx $40 million per year until the resolution of the patent litigation. Pet. App. 8a. In *Valley Drug*, Abbott paid Geneva $54 million per year until the patent litigation ended and Zenith $12-24 million per year until Abbott's patent expired. Pet. App. 125a-126a.) In both, the district courts granted the plaintiffs' partial summary judgment motions, concluding that the agreements were unlawful *per se*. Pet. App. 13a-14a, 127a. In both, the question on appeal was whether to apply the *per se* rule.

The Sixth Circuit disposed of the issue in a few paragraphs. Pet. App. 17a-21a. It asserted: "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade." Pet. App. 18a. It dispensed with the patentee's right to exclude Andrx from the market in one sentence: "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. 19a (footnote and citation omitted). As to Andrx's contention that the exclusionary effect of the Stipulation was, if anything, narrower than that of HMR's patent, the court responded, Andrx's "claims that the [Stipulation] lacked anticompetitive effects and had

procompetitive benefits are **simply irrelevant**." Pet. App. 19a-20a (emphasis added).

The Eleventh Circuit acknowledged that "[t]he terms of the agreements at issue in the *Cardizem* case were similar to the terms of the Agreements in this case," but took "the opposite view." Pet. App. 145a & n.25. After an extensive analysis and discussion, it held that under the antitrust laws restraints are generally tested under the rule of reason, that *per se* condemnation is reserved for those rare restraints that are "obviously anticompetitive," and that, even under a *per se* analysis the court must form a judgment about "the competitive significance of the restraint at issue." Pet. App. 132a. With this framework in mind, the court concluded: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent." Pet. App. 133a. The court held that because the generic companies' agreements to remain out of the market "appear[] to be no broader than the potential exclusionary effect of the '207 patent" they fall within "the heart of the patent right and cannot trigger the per se label." Pet. App. 135a-136a.

The Eleventh Circuit considered the patentee's payments irrelevant:

> If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. . . . To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate

> accommodation of the competing policies of the patent and antitrust laws.

Pet. App. 143a. The Eleventh Circuit expressly recognized the circuit split, concluding "we respectfully disagree."

> We recognize that the Sixth Circuit appeared to take the opposite view . . . . When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "The protection of the patent laws and the coverage of the antitrust laws are not separate issues." [*United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981).] As the above discussion indicates, we do not think that a payment from the patentee . . . should be automatically condemned under the antitrust laws.

Pet. App. 145a-146a & n.26. The court then rejected both *per se* and rule of reason treatment; the court held that a patent infringement settlement is necessarily lawful under the antitrust laws if the restraint that it imposes on an alleged infringer is no greater than the restraint that the patentee could plausibly secure from a court. Pet. App. 147a & n.27.

II. If the Circuit Split Is Not Resolved, the Lower Courts Will Continue To Apply Radically Inconsistent Rules to Patent Settlements

A. Other Antitrust Challenges to Patent Infringement Settlements Will Soon Reach the Appellate Courts

Without this Court's intervention, the issue that divided the Sixth and Eleventh Circuits will recur. Indeed, a number of antitrust challenges to patent infringement settlements have already resulted in district court decisions that will soon be reviewed by the Courts of Appeals for the District of Columbia Circuit, Second Circuit, and Seventh Circuit.

In a survey of the pharmaceutical industry, the FTC identified many agreements indistinguishable from those addressed in *Cardizem* and *Valley Drug*. *See FTC Generic Entry Study*. Some of these agreements are currently being challenged by competitors, purchasers in multidistrict litigation, and the FTC staff in administrative proceedings. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, ___ F. Supp. 2d ___, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), *appeal docketed sub nom. Tamoxifen Citrate v. Barr Labs., Inc.*, No. 03-7641 (2d Cir. June 20, 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro*"); *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2002 WL 1488085 (ALJ Decision June 27, 2002); *see also* FTC, *Bristol-Myers Squibb Co.: Analysis to Aid Public Comment*, 68 Fed. Reg. 12080, 12081-82 (March 13, 2003) (describing FTC's complaint regarding agreement in which the generic company abandoned its patent challenge and conceded the patent's validity in exchange for a $72.5 million payment by the brand company). These cases will lead to more appeals on the precise question at issue here.

In *Asahi*, Judge Posner (of the Seventh Circuit, sitting by designation), held that a patent litigation settlement cannot be condemned based on the presence of "reverse" compensation, especially where it may have "led to increased competition." *Asahi*, 2003 WL 22462405 at *6.[2] Judge Posner criticized the Sixth Circuit's *per se* condemnation of "reverse payments," noting that "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Id.*

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[2] We note that Judge Posner is the author of many leading scholarly works on antitrust law. *See, e.g.*, Richard A. Posner, *Antitrust Law* (2d ed. 2001); Richard A. Posner, *Antitrust and the New Economy*, 68 Antitrust L.J. 925 (2001).

Judge Posner added: "A ban on reverse-payment settlements would **reduce** the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought **anti**competitive." *Id.* (emphasis added). He then observed that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Id.* (emphasis in original).

In *Tamoxifen*, the district court dismissed claims alleging that the brand company's payment of $21 million to a generic company that agreed to vacate a judgment of invalidity, keep its own generic off the market, and sell a more expensive licensed version instead, violated the Sherman Act. *Tamoxifen*, 277 F. Supp. 2d at 125-26. The *Tamoxifen* plaintiffs have appealed to the Second Circuit, where a motion to transfer the appeal to the Federal Circuit has been referred to the merits panel. *Tamoxifen Citrate v. Barr Labs., Inc.*, No. 03-7641 (2d Cir. June 20, 2003).

In *Cipro*, the district court held that it was not a *per se* violation of the Sherman Act for a brand company to pay $398 million for an agreement to keep a generic product off the market. *Cipro*, 261 F. Supp. 2d at 196. The *Cipro* court rejected the plaintiffs' contention that "reverse payments" render a patent infringement settlement *per se* illegal and noted that "even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer." *Id.* at 252. The *Cipro* court concluded that "when patents are involved, case law directs that the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal." *Id.* at 249.

In *Schering-Plough,* the FTC staff argued that "reverse payments" are *per se* unlawful, but the FTC Administrative

Law Judge (ALJ) rejected that approach because it would have inappropriately required the court to presume that the patent infringement suit lacked merit and involved application of a *per se* rule to a new practice. *Schering-Plough*, 2002 WL 1488085 at 3, 65, 67. The ALJ concluded that a brand payment does not take a patentee "beyond the rights conferred by the patent" and held that, "because an agreement to settle patent litigation must be examined in the context in which the agreement arose, the *per se* approach is not appropriate" *Id.* at 64, 67. On appeal to the full Commission, the staff has argued that the Commission should follow the *Cardizem per se* holding, which the FTC staff described as arising from an agreement "similar" to those in *Schering-Plough*. *See In re Schering-Plough*, Appeal Brief Of Counsel Supporting the Complaint at 42, August 9, 2002 (2002 WL 1941700). The staff's appeal is pending. *See* FTC Docket 9297 (at www3.ftc.gov/os/adjpro/d9297/index.htm).

Even were the issue limited to the pharmaceutical industry, it would not end with *Cardizem*, *Valley Drug*, *Asahi*, *Tamoxifen*, *Cipro*, and *Schering-Plough*. The use of brand payments (*i.e.*, consideration) has been a widespread pharmaceutical industry practice affecting many products generating billions of dollars in total annual revenues. Accordingly, the cottage industry that is now developing to seek antitrust damages for this practice will likely flourish.

Brand payments have been used to settle 50% of resolved patent cases involving "blockbuster" drugs. *See FTC Generic Entry Study* at 26, 28. Even more cases settled using other consideration such as "delayed licenses," which the FTC staff has erroneously condemned as *per se* unlawful using the same reasoning employed in challenges to brand payments. *See id.* at 29, 34; *Schering-Plough*, 2002 WL 1488085 at 64. Brand payments have exceeded $500 million and have resolved challenges to products generating total annual revenues in excess of $4 billion. *See FTC Generic*

Entry Study at 25, 32, 35. One-third of brand companies and 20% of generic companies have used "brand payments" or "delayed licenses." *Id.* at 3, 34.

The current legal uncertainty could affect pharmaceutical products generating as much as $20 billion in annual revenue. *See Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 2 (11th Cir. Oct. 6, 2003). On average, generic drug manufacturers file more than 500 ANDAs per year. *See FTC Generic Entry Study* at 10. In recent years, approximately 20% of those ANDAs contained Paragraph IV certifications challenging brand companies' patent claims. *Id.* These Paragraph IV ANDAs often challenge "blockbuster" drugs that generate billions of dollars in annual revenue for brand companies and finance their innovation efforts. *See id.* at 10-11. In such cases, patent litigation between the brand and generic is a virtual certainty, and the incentives to settle are great. *Id.* at 14, 18. Given the circuit split and likelihood of continued litigation, this Court should grant certiorari.

B. The Issue Is Not Confined to the Pharmaceutical Industry

The circuit split does not merely concern an issue of particular interest to the pharmaceutical industry; it implicates all patent infringement settlements. The payments in *Cardizem* and *Valley Drug* merely highlight the consideration that generally flows to infringers in patent settlements. "Payments" may take various forms (*e.g.*, a release of damages already incurred or a future license). As "payments" by patentees to infringers play a critical role in settling patent litigation generally, the Sixth Circuit's erroneous holding will lead to antitrust suits challenging non-pharmaceutical patent infringement settlements.

In most infringement suits, the alleged infringer causes the intellectual property owner at least some harm before the suit is filed, so that the property owner has "a damages claim to bargain with" during settlement discussions that will

ensure that some consideration flows to the infringer. *See* Pet. App. 143a. A patent holder's release of the infringer from some or all of the patentee's damage claim in exchange for the infringer's promise to exit the market is consideration indistinguishable from a brand payment. *See Asahi*, 2003 WL 22462405 at *6 ("*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement") (emphasis in original); *Cipro*, 261 F. Supp. 2d at 252 ("even in the traditional context, implicit consideration flows from the patent holder to the alleged infringer"); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 772 (2003) ("When an infringement plaintiff accepts a discount on the value of its lost-monopoly rent damages claim in exchange for the certainty of recovering some portion of its damages plus the certainty that the allegedly infringing use will cease, it has effectively bought out the possibility of competition that would destroy the value of its patent monopoly. This is no different than if the patentee paid a potential new entrant – and potential infringer – not to enter the market and begin the allegedly infringing conduct.").

Litigants are already beginning to extend the rationale underlying *Cardizem* to its logical but dangerous conclusion. For example, the FTC staff has contended that it is unlawful *per se* for a patentee to share the monopolistic rents generated by a patent through a brand payment **or** through a temporal division of the patent's lifespan. *See* FTC, *Generic Entry Study* at 29, 34; *Schering-Plough*, 2002 WL 1488085 at 64. Thus, using the FTC staff's theory, it is a *per se* violation of the Sherman Act for a patentee and an alleged infringer to settle an infringement suit concerning a patent due to expire in ten years by agreeing that the infringer will remain out of the market for the first five years and receive a royalty-free license to enter the market during the last five years.

Like other types of litigation, 96% of patent infringement cases are resolved before trial, with the vast majority settled. *See* Federal Judicial Caseload Statistics, Table C-4 U.S. District Courts – Civil Cases Terminated, by Nature of Suit and Action Taken, During the 12-Month Period Ending March 31, 2002 (March 31, 2002) (at www.uscourts.gov/caseload2002/contents.html); Gauri Prakash-Canjels, *Trends in Patent Cases: 1990-2000*, 41 IDEA 283, 290-91 (2001). The Sixth Circuit's ban on patent infringement settlements in which the alleged infringer is paid to remain out of the market will turn many of these settlements into *per se* violations of the antitrust laws. This Court should grant review to avert this result, and to clarify the circumstances under which antitrust liability may attach to settlements of intellectual property litigation.

C. The Multidistrict Nature of Antitrust Challenges to Patent Infringement Settlements Exacerbates the Circuit Split

Antitrust litigation challenging patent infringement settlements is typically multidistrict in nature. As a result, disputes will arise throughout the Nation, even within the Sixth and Eleventh Circuits, regarding what law to apply. This is a further reason why this Court's review is urgently needed.

This case provides an example. Andrx is based in Florida, within the Eleventh Circuit. The principal case in this multidistrict litigation was filed in the Southern District of Florida and will return there in a few months when pre-trial proceedings are complete. *See* 28 U.S.C. § 1407; *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). If this Court denies certiorari, the Florida Plaintiffs will likely argue to the Florida trial court that the Sixth Circuit's decision should govern under the law of the case doctrine. But the Florida court would be bound to follow the law of the Eleventh Circuit, as set forth in *Valley Drug*. *See Murphy v. FDIC*, 208 F.3d 959, 966 (11th Cir.

2000). Accordingly, if this Court fails to resolve the conflict in the circuits, the Florida court may find itself "'suspended between the doctrine of stare decisis and the doctrine of law of the case. In such a circumstance the . . . court would invite reversal if it did not follow the decisions of its own court of appeals.'" *Moore v. Valder*, 65 F.3d 189, 195 n.9 (D.C. Cir. 1995) (citation omitted).

Similar scenarios may unfold in *Valley Drug* and the other multidistrict actions arising from antitrust challenges to patent infringement suit settlements. Two *Valley Drug* cases originated in Michigan within the Sixth Circuit. *See* Docket Sheets for *Blue Cross of Michigan v. Abbott Labs.*, 01-CV-95 (W.D. Mich.) and *Bernstein v. Abbott Labs.*, 01-CV-72974 (E.D. Mich.). While the complaints filed there were superseded, the Michigan plaintiffs may well seek a remand and the application of *Cardizem*. Cases consolidated in *Cipro* and *Tamoxifen* also originated in Michigan, within the Sixth Circuit, and Florida, within the Eleventh Circuit. *See* Docket Sheets for *McIntyre v. Bayer AG*, 00-CV-60361 (E.D. Mich.), *Loesch v. Bayer AG*, 00-CV-7738 (S.D. Fla.), *Bennish v. Barr Labs. Inc.*, 00-CV-74949 (E.D. Mich.), *Maloney v. Barr Labs.*, 01-CV-4187 (S.D. Fla.), and *Blonstein v. Barr Labs.*, 01-CV-8399 (S.D. Fla.). Thus, because of the circuit split, there is uncertainty even within the Sixth and Eleventh Circuits, and the potential for further wasteful litigation. The need for this Court's review is, therefore, exceptionally pressing.

III. The Question Presented Is One of Great Importance

The issue that is the subject of the circuit split is one of vital importance to the Nation. At the points where intellectual property and antitrust enforcement intersect, the congressional balance between the interests of innovators, would-be competitors, and consumers must be carefully maintained. *See* Assistant Attorney General R. Hewitt Pate, Antitrust Division, *Antitrust and Intellectual Property*, Address to the American Intellectual Property Law

Association at 3 (2003) [hereinafter *Antitrust & Intellectual Property*](at www.usdoj.gov/atr/public/speeches/200701.pdf) ("Calls for more aggressive antitrust enforcement as a vehicle for cabining the enjoyment of intellectual property rights should . . . be viewed with great caution.").

Blunderbuss application of the judge-made *per se* rule in such circumstances has grave implications for innovation and competition. For example, when patents cannot be readily enforced through settlements, the brand pharmaceutical companies upon which we rely to discover new critical medicines are discouraged from making necessary investments. Pet. App. 143a-144a. In addition, if generic companies cannot be compensated for agreeing to settle their weaker patent infringement challenges, there will be fewer patent challenges and less competition in the long-run. *Asahi*, 2003 WL 22462405 at *6.

While some have challenged this logic – arguing that a *per se* rule is a critical means of protecting consumer access to affordable medicine – there is unanimous agreement that the issue is one of "vital public importance." *Valley Drug Co. v. Abbott Labs.*, No. 02-12091-J, Appellees' Petition for Rehearing En Banc at 2 (11th Cir. Oct. 6, 2003); *see also* then-FTC Chairman Robert Pitofsky, Statement of the FTC Before the House Judiciary Committee at 10 (2000) (at www.ftc.gov/os/2000/04/antitrusttimony.htm) (describing the "drug settlement cases" as "a tremendously important area, with high stakes to consumers").

As applied to the pharmaceutical industry, where there is intense public interest in pharmaceutical innovation and medical costs, the question of whether brand and generic pharmaceutical companies can settle their patent disputes is of such national importance that it has generated widespread media attention. *See, e.g.*, Jayne O'Donnell, *FTC Targets Deal to Keep Generic Off Shelf*, USA Today, Sept. 30, 1999, at Money, 1B (discussing *Cardizem*); Robert Pear, *AARP Wants Bigger Role in Prescription Drug Cases*, N.Y. Times,

April 23, 2002, at A14 (describing issue as "a political minefield" and quoting former FTC official as describing "agreements between brand-name and generic drug manufacturers to settle patent litigation" as the "hottest area in health care antitrust law – indeed, arguably in all of antitrust"); Peter Spiegel, *U.S. To Widen Drug Groups Inquiry: FTC Investigation Could Lead to New Wave of Lawsuits*, Financial Times (London), July 6, 2001, at 17 (discussing FTC investigations of agreements in *Cardizem*, *Valley Drug*, and *Schering-Plough*); Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics And Keep Themselves Healthy*, N.Y. Times, July 23, 2000, Section 1 at page 1 (discussing *Cardizem*).

A. The Sixth Circuit's Decision Upsets the Critical Balance Between the Patent and Antitrust Laws

The Sixth Circuit's decision dispenses with basic principles underlying the patent and antitrust laws. The departure from accepted precepts has grave implications for innovators and patent challengers.

Contrary to the Sixth Circuit's assertion (Pet. App. 19a), a patentee's legal monopoly rights extend beyond bringing good-faith patent infringement actions, seeking preliminary injunctions, and collecting damages from infringers. The patent laws "reward[] innovation with a temporary monopoly." *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002). A patent holder is entitled to a "limited patent monopoly under the Constitution." *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1966). It is not a mere ticket to enter a courthouse and seek judicial relief for infringement. The government-issued patent itself – not the court order enforcing it – is the "grant of an exclusive right to an invention," *id.* at 9, "expressly sanctioned by the Constitution." *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 330 & n.20 (1971). Indeed, Congress has explicitly provided that, even without

further taxing the scarce resources of the federal courts, a patent holder has a statutory "right to exclude others from making, using, offering for sale, or selling the invention," and may use licensing arrangements to enter into what in other contexts would be condemned as unlawful horizontal market allocation agreements. *See* 35 U.S.C. §§ 154(a)(1), 261.

The Sixth Circuit's assumption that these principles can be ignored when assessing the legality of a patent infringement settlement under the antitrust laws is incorrect. The Sherman Act only prohibits *unreasonable* restraints of trade. *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988). Generally, the reasonableness of a restraint on trade must be analyzed under a rule of reason requiring an assessment and weighing of anticompetitive and procompetitive effects. *Id.* at 726. The only exceptions are in those narrow circumstances in which "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" such that a form of truncated analysis, including the *per se* rule's outright ban, may be employed. *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

The Sixth Circuit erred in condemning the Stipulation as *per se* illegal without any inquiry into whether, in light of HMR's patent, it was actually anticompetitive in any respect, and without regard to its procompetitive benefits. This Court has recently explained that, before determining "whether the experience of the market" is such that "a confident conclusion about the principal tendency of a restriction" can be reached without a rule of reason analysis, the court must consider "the circumstances, details, and logic of [the] restraint" and reach conclusions about "whether the effects **actually are anticompetitive**." *California Dental*, 526 U.S. at 775 n.12, 781 (emphasis added). As Judge Easterbrook has explained: "The question whether a restraint is 'naked'

requires some knowledge of its effects. . . . In recent years, the *per se* inquiry has required more and more economic exposition. There is no longer any real 'shortcut' to condemnation." Frank H. Easterbrook, *The Limits of Antitrust*, 63 Texas L. Rev. 1, 18-19 (1984); *see also Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 297-98 (1985) (requiring for *per se* characterization a "satisfactory threshold determination whether anticompetitive effects would be likely"). Given that "assumption alone will not do," *California Dental*, 526 U.S. at 775 n.12, the Sixth Circuit should have, at a minimum, considered "the strength of the patent" (*Asahi*, 2003 WL 22462405 at *4), evaluated the foreclosure that flowed from the valid exercise of the patentee's patent rights, and considered the FDA's determination that prudent generics have never entered at risk and the FTC's determination that the very Stipulation under consideration did not lead to "any delay in the entry into the market of a generic version of Cardizem CD," *see* 66 Fed. Reg. 18636, 18638 (April 10, 2001) – rather than ignoring all of this as "irrelevant." Pet. App. 19a-20a.

This Court's directive to consider actual anticompetitive effects is particularly important when dealing with patent settlements. When an antitrust case "concerns articles protected by letters patent," the patentee's monopoly rights must be the "first important and most material fact." *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 88 (1902). Antitrust law must accommodate the monopolies created by our intellectual property laws because intellectual property – such as patented medicines – "exists at all only because of [those] laws." *BMI v. CBS*, 441 U.S. 1, 18-20 (1979).

It follows from the antitrust law's accommodation of intellectual property rights that an owner of intellectual property must be able to enter into "any market arrangements reasonably necessary to effectuate the rights that are granted"

without being deemed to have engaged in "a *per se* violation of the Sherman Act." *See BMI*, 441 U.S. at 18; *see also B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997) (restraints allegedly exceeding "scope of the patent" "must be evaluated under the rule of reason"); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) (question is "whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason"). This includes a "settlement by agreement, rather than litigation," to resolve "legitimately conflicting claims or threatened [patent] interferences"; an arrangement that this Court has held "is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

The Stipulation was an interim settlement, "reasonably necessary to effectuate" HMR's patent rights. Accordingly, it should have been evaluated under the rule of reason. *See BMI*, 441 U.S. at 18. If such a settlement could be condemned *per se*, without any consideration of the exclusionary impact of the patent, consumers could seek antitrust damages resulting from their inability to purchase patent-infringing products. If, as the *per se* ruling suggests, antitrust policy is used to promote **infringing** competition, there will be diminished innovation and fewer new products to protect. *See In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (court must give "'due consideration to the exclusivity that inheres in the patent grant'"), *cert. denied*, 531 U.S. 1143 (2001); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("some measure must guarantee that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws") (internal quotation omitted).

It is for this Court, not Congress, to correct the Sixth Circuit's error about the type of antitrust analysis that should govern patent infringement settlements. The *per se* rule is "a judicial gloss" on the Sherman Act; the statute, after all, only

condemns unreasonable restraints. *See Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 49-50 (1977). Since "[i]t was the courts, not the Congress, that created the concept of per se rules" and "a rule of reason," it "has historically been the role and function of the Supreme Court" to determine which method to apply in particular types of cases. *See* William F. Baxter, *Vertical Practices*, 52 Antitrust L.J. 743, 751 (1983). This Court should grant certiorari to clarify that it is not a *per se* violation of the antitrust laws for a patentee to protect its patent rights by paying a patent infringer to remain out of the market during the life of the patent.

B. The Sixth Circuit's Decision Devalues Intellectual Property Rights

If a patentee may not "bolster" a patent grant with a payment to an infringer to induce compliance with the statutory monopoly without incurring antitrust liability, it follows that the statutory "right to exclude others," 35 U.S.C. § 154(a)(1), has no practical value to a patentee until a court enforces it, and that the patent is devalued by the costs and risks of litigation. Recognizing the implications of such a holding, major associations of intellectual property owners, such as the American Intellectual Property Law Association and the Intellectual Property Owners Association, have argued that, payments by patentees notwithstanding, intellectual property settlements should be reviewed under the rule of reason. *See* AIPLA, *Testimony Before FTC and Antitrust Division on Antitrust & Intellectual Property Issues* 9) (April 10, 2002) (at www.ftc.gov/os/comments/intelpropertycomments) (observing that the district courts in *Cardizem* and *Valley Drug* "held settlement agreements illegal under a *per se* rule" and arguing that "applying a *per se* rule to litigation settlements is unwise and inappropriate"); IPO, *Comments on the Joint Hearings of the FTC and DOJ Regarding Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy* 10 (Nov. 15, 2002) (at www.ftc.gov/os/comments/intelpropertycomments)

("Central to the legitimacy of [intellectual property] settlements is the issue of whether the alleged infringer would be able to compete absent a license. In order to apply a *per se* rule to an intellectual property settlement, a court must, in effect, assume that the intellectual property owner would lose the infringement suit – an assumption that no court is entitled to make without a trial of the infringement issue, or a finding of clear and convincing evidence to overcome the statutory presumption of validity of issued patents. For these reasons, we believe that, absent a fraudulent intellectual property right or a sham lawsuit or settlement, intellectual property settlements should be analyzed under the rule of reason.") .

The damage inflicted by the Sixth Circuit's decision on incentives to innovate is particularly acute in the pharmaceutical industry. Indeed, since the first patent infringement settlement was condemned as *per se* unlawful by the district court in *Cardizem*, the prime indicator of pharmaceutical innovation has declined steadily from its peak in 2000 by 5%-9% every year. *See IND Filings Hit Seven-Year Low in 2003; Where is R&D Productivity,* Prescription Pharma. & Biotechnology ("The Pink Sheet") 8 (Nov. 10, 2003). It is likely that brand companies' inability to settle patent infringement suits is contributing to the current "research slump." *See* Matthew Herper, *Solving the Drug Patent Problem,* Forbes.com (May 2, 2002) (at www.forbes.com/2002/05/02/0502patents.html) (arguing that slump is attributable to "long battles over dozens of patents" that "distract pharmaceutical companies from their job: making new medicines"). Given the importance of patents to the industry, the Pharmaceutical Research and Manufacturers of America have joined the other intellectual property owners in opposing a *per se* ban on payments by patent holders to infringers in patent settlements. *See* PhMRA, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights* 38 (April 22, 2002) (at www.ftc.gov/os/comments/

intelpropertycomments) ("Unless the underlying infringement claim is objectively baseless or the settlement would produce a result outside the spectrum of possible litigation outcomes, settlements should not be subject to antitrust liability."); *see also In re: Cardizem CD Antitrust Litig.*, No. 00-2482, Brief of Amicus Curiae PhMRA (6th Cir. April 16, 2000); *In re: Cardizem CD Antitrust Litig.*, No. 00-2482, Brief of Amicus Curiae Generic Pharm. Ass'n (6th Cir. April 16, 2000).

C. The Issue Has Been Fully Debated and Is Ripe For Resolution

For the past five years, the antitrust enforcement agencies and the antitrust scholars have debated whether patentee payments in patent infringement settlements should be *per se* unlawful or evaluated under the rule of reason. Indeed, the question of how the antitrust law should accommodate intellectual property interests has been at the forefront of discussions in that community. *See generally* Assistant Attorney General R. Hewitt Pate, *Antitrust & Intellectual Property* at 1 (the intersection of antitrust and intellectual property is the "'issue du jour' among antitrust practitioners"). The debate has run its course, and this Court's intervention is now needed.

The Department of Justice's Antitrust Division never sought a *per se* ban. This year, it stated that enforcement actions would continue to account for exclusionary effects of patents and procompetitive benefits of settlements:

> These [Hatch-Waxman] cases present especially tough problems for [antitrust] enforcers. First, these cases occur in the context of conduct the law generally favors – the settlement of litigation. Second, **assessing the competitive significance of settlements often depends on an evaluation of the underlying strength of patent rights**. If a patent is valid and infringed, then any competitive entry allowed by a

> settlement is up to the patent holder. If a patent is invalid and not infringed, then there should be no impediment to competitive entry whatsoever.

Id. at 12 (emphasis added).

While the FTC staff has sought a *per se* ban, the Commission has proceeded more cautiously, authorizing an extensive study of brand-generic patent litigation settlements based on an industry survey. *See generally FTC Generic Entry Study*. Several FTC Commissioners debated the issue publicly. For example, Commissioner Leary stated that he would be "tempted to support a presumption that reverse payments are illegal," but "would not suggest at this stage that the presumption be conclusive (which would be another way of saying reverse payments are illegal *per se*)." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Part II*, 5 (2001) (at www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm). On the other hand, then-Commissioner Anthony argued that, because "settlements between monopolists and would-be entrants are ripe for collusive dealings," "[p]atent litigation, which tests and reveals the validity of a patent, should be allowed to run its course." Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property* 4-6 (2000) (at www.ftc.gov/speeches/anthony/sfip000601.htm).

Leading antitrust scholars (including Judge Posner, *see Asahi*, 2003 WL 22462405) have also weighed in, maintaining that *per se* treatment is inappropriate. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, Antitrust Bull. 491, 539 (Summer-Fall 2002) ("these settlements cannot be characterized as naked market allocation schemes and, therefore, are not ripe for *per se* treatment"); Yee Wah Chin & Thomas G. Krattenmaker, *Antitrust Update*, M&A Tax J. 30, 38 (December 2001) ("appropriate test of the legality under the antitrust laws of such arrangements settling

intellectual property disputes should not be a *per se* test"); Thomas F. Cotter, *Refining the "Presumptive Illegality": Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 Minn. L. Rev. 1789, 1802 (2003) ("*per se* treatment of reverse payment settlements is inappropriate, because these agreements also have some potential to enhance rather than impede efficiency"); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 797 (2003) ("Exit payments should . . . be permitted when the patentee's claims appear *ex ante* to have substantial merit and disallowed when they are likely to fail."); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L. J. 777, 806 (2003) ("existence of procompetitive reasons for partial settlement payments from brand-name manufacturers to the generics indicates that a strict *per se* illegal treatment of such payments is inappropriate"); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 Antitrust 68, 75 (Spring 2003) (Hatch-Waxman settlements should be analyzed under a "rule of reason analysis, which begins by measuring the patent").[3]

Given the extent of the public discourse that these agreements have generated over the past five years, the issue is now ripe for this Court's review. This Court should grant certiorari to consider whether *per se* antitrust enforcement of

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[3] Others have argued in favor of a *per se* ban. *See, e.g.*, Keith Leffler & Cristopher Leffler, *The Probabilistic Nature of Patent Rights*, 17 Antitrust 77, 78 (Summer 2003); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003); Peter J. Prommer, *Note: The Pioneer and Generic Drug Manufacturer Agreements: Is the Sherman Act Big Enough to Swallow These Pills?*, 2002 J. L. Tech. & Pol'y 215, 232-33 (Spring 2002).

intellectual property settlements will undermine the objectives Congress sought to achieve in the patent laws.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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November 21, 2003

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-2483

In Re: CARDIZEM CD ANTITRUST LITIGATION,
LOUISIANA WHOLESALE DRUG CO., ET AL.,

Plaintiffs-Appellees,

—v.—

HOECHST MARION ROUSSEL, INC.,
and ANDRX PHARMACEUTICALS, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the
Eastern District of Michigan at Detroit.

No. 99-01278—Nancy G. Edmunds, District Judge.

Argued: April 30, 2002

Decided and Filed: June 13, 2003

Before:

SILER and CLAY, *Circuit Judges*;
OBERDORFER, *District Judge*.*

OBERDORFER, District Judge. This antitrust case arises out of an agreement entered into by the defendants, Hoescht Marion Roussel, Inc. ("HMR"), the manufacturer of the prescription drug Cardizem CD, and Andrx Pharmaceuticals, Inc. ("Andrx"), then a potential manufacturer of a generic version of that drug. The agreement provided, in essence, that Andrx, in exchange for quarterly payments of $10 million, would refrain from marketing its generic version of Cardizem CD even after it had received FDA approval (the "Agreement"). The plaintiffs are direct and indirect purchasers of Cardizem CD who filed complaints challenging the Agreement as a violation of federal and state antitrust laws. After denying the defendants' motions to dismiss, *see In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) ("Dist. Ct. Op. I") and granting the plaintiffs' motions for partial summary judgment, *id.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000) ("Dist. Ct. Op. II"), the district court certified two questions for interlocutory appeal:

> (1) . . . In determining whether Plaintiffs have properly pled antitrust injury, does the language of the Sixth Circuit's decisions in *Valley Products Co. v. Landmark*, 128 F.3d 398, 404 (6th Cir. 1997) and *Hodges v. WSM, Inc.*, 26 F.3d 36, 39 (6th Cir. 1994) require dismissal of Plaintiffs' antitrust claims at

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* The Honorable Louis F. Oberdorfer, United States District Judge for the District of Columbia, sitting by designation.

> the pleading stage if Plaintiffs cannot allege facts showing that Defendants' alleged anticompetitive conduct was a "necessary predicate" to their antitrust injury; *i.e.*, that dismissal is required unless Plaintiffs plead facts showing that the alleged antitrust injury could not possibly have occurred absent Defendants' alleged anticompetitive conduct?
>
> (2) . . . In determining whether Plaintiffs' motions for partial judgment were properly granted, whether the Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the corresponding state antitrust laws at issue in this litigation.

JA 607. Our answers, explained more fully herein, are as follows:

Answer to First Certified Question: As framed, the certified question is not susceptible to a yes or no answer because it incorporates a definition of "necessary predicate" that we reject. *Hodges* and *Valley Products* stand for the proposition that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege that the antitrust violation is *either* the "necessary predicate" for its injury *or* the only means by which the defendant could have caused its injury. Under the "necessary predicate" option, dismissal is warranted only where it is apparent from the allegations in the complaints that the plaintiffs' injury would have occurred even if there had been no antitrust violation. Here, Andrx could have made a unilateral and legal decision to delay its market entry, but the plaintiffs have alleged it would not have done so but for the Agreement and HMR's payment to it of $40 million per year. The

plaintiffs' allegations satisfy the "necessary predicate" test. The defendants' claim that Andrx's decision to stay off the market was motivated not by the $40 million per year it was being paid by HMR, but by its fear of damages in the pending patent infringement litigation, merely raises a disputed issue of fact that cannot be resolved on a motion to dismiss. Accordingly, the district court properly denied the defendants' motions to dismiss for failure to allege antitrust injury.

Answer to Second Certified Question: Yes. The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws. Accordingly, the district court properly granted summary judgment for the plaintiffs on the issue of whether the Agreement was *per se* illegal.

I. BACKGROUND

As the district court has set forth a complete outline of the relevant statutory framework, *see* Dist. Ct. Op. I, at 627-29; Dist. Ct. Op. II, at 685-86, facts, *see* Dist. Ct. Op. I, at 629-32; Dist. Ct. Op. II, at 686-89, and procedural history, *see* Dist. Ct. Op. I, at 632-33; Dist. Ct. Op. II, at 689-90, we repeat here only what is necessary to our analysis of the issues on appeal.

A. Statutory Framework

In 1984, Congress enacted the Hatch-Waxman Amendments, *see* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399. Those amendments permit a

potential generic[1] manufacturer of a patented pioneer drug to file an abbreviated application for approval with the Food and Drug Administration ("FDA") (known as an Abbreviated New Drug Application ("ANDA")). *See* 21 U.S.C. § 355(j)(1). Instead of submitting new safety and efficacy studies, an ANDA may rely on the FDA's prior determination, made in the course of approving an earlier "pioneer" drug, that the active ingredients of the proposed new drug are safe and effective. *Id.* § 355(j)(2)(A). Every ANDA must include a "certification that, in the opinion of the applicant and to the best of his knowledge, the proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug." *Id.* § 355(j)(2)(A)(vii). That certification can take several forms. Relevant here is the so-called "paragraph IV certification" whereby the applicant certifies that any such patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). An applicant filing a paragraph IV certification must give notice to the patent-holder, *id.* § 355(j)(2)(B); the patent-holder then has forty-five days to file a patent infringement action against the applicant. *Id.* § 355(j)(5)(B)(iii). If the patent-holder files suit, a thirty-month stay goes into effect, meaning that unless before that time the court hearing the patent infringement case finds that the patent is invalid or not infringed, the FDA cannot approve the generic drug before the expiration of that thirty-month period. *Id.* § 355(j)(5)(B)(iii)(I). In order to encourage generic

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[1] A "generic" drug contains the same active ingredients but not necessarily the same inactive ingredients as a "pioneer" drug sold under a brand name. *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983).

entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180-day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications. *Id.* § 355(j)(5)(B)(iv). The 180-day period of exclusivity begins either (1) when the first ANDA applicant begins commercial marketing of its generic drug (the marketing trigger) or (2) when there is a court decision ruling that the patent is invalid or not infringed (the court decision trigger), whichever is earlier. *Id.*

B. Facts

Unless otherwise noted, the following facts are undisputed. HMR manufactures and markets Cardizem CD, a brand-name prescription drug which is used for the treatment of angina and hypertension and for the prevention of heart attacks and strokes. The active ingredient in Cardizem CD is diltiazem hydrochloride, which is delivered to the user through a controlled-release system that requires only one dose per day. HMR's patent for diltiazem hydrochloride expired in November 1992.

On September 22, 1995, Andrx filed an ANDA with the FDA seeking approval to manufacture and sell a generic form of Cardizem CD. On December 30, 1995, Andrx filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA as covering Cardizem CD. Andrx was the first potential generic manufacturer of Cardizem CD to file an ANDA with a paragraph IV certification, entitling it to the 180-day exclusivity period once it received FDA approval.

In November 1995, the United States patent office issued Carderm Capital, L.P. ("Carderm") U.S. Patent

No. 5,470,584 (" '584 patent"), for Cardizem CD's "dissolution profile," which Carderm licensed to HMR. JA 1796-1810. The dissolution profile claimed by the '584 patent was for 0-45% of the total diltiazem to be released within 18 hours ("45%-18 patent").[2]

In January 1996, HMR and Carderm filed a patent infringement suit against Andrx in the United States District Court for the Southern District of Florida, asserting that the generic version of Cardizem CD that Andrx proposed would infringe the '584 patent. *See* JA 1240-1257 (Complaint, *Hoescht Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc.*, No. 96-06121 (S.D. Fla. filed Jan. 31, 1996)). The complaint sought neither damages nor a preliminary injunction. *Id.* However, filing that complaint automatically triggered the thirty-month waiting period during which the FDA could not approve Andrx's ANDA and Andrx could not market its generic product. In February 1996, Andrx brought antitrust and unfair competition counterclaims against HMR. JA 1717-47. In April 1996, Andrx amended its ANDA to specify that the dissolution profile for its generic product was not less than 55% of total diltiazem released within 18 hours ("55%-18 generic"). HMR nonetheless continued to pursue its patent infringement litigation against Andrx in defense of its 45%-18 patent. On June 2, 1997, Andrx represented to the patent court that it intended to market its generic product as soon as it received FDA approval. JA 1758.

On September 15, 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period in early July

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[2] Two other patents for the dissolution profile of Cardizem CD had previously been issued, one in February 1994 and one in August 1995. Neither is relevant to the present litigation.

1998, or earlier if the court in the patent infringement action ruled that the '584 patent was not infringed.

Nine days later, on September 24, 1997, HMR and Andrx entered into the Agreement. JA 1363-73. It provided that Andrx would not market a bioequivalent or generic version of Cardizem CD in the United States until the earliest of: (1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; *or* (3) HMR entering into a license agreement with a third party. Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, to diligently prosecute its ANDA, and to not "relinquish or otherwise compromise any right accruing thereunder or pertaining thereto," including its 180-day period of exclusivity. In exchange, HMR agreed to make interim payments to Andrx in the amount of $40 million per year, payable quarterly, beginning on the date Andrx received final FDA approval.[3] HMR further agreed to pay Andrx $100 million per year,[4] less whatever interim payments had been made, once: (1) there was a final and unappealable determination that the patent was not infringed; (2) HMR dismissed the patent infringement case; or (3) there was a final and unappealable deter-

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[3] The payments were scheduled to end on the earliest of: (1) a final and unappealable order or judgment in the patent infringement case; (2) if HMR notified Andrx that it intended to enter into a license agreement with a third party, the earlier of: (a) the expiration date of the required notice period or (b) the date Andrx effected its first commercial sale of the Andrx product; or (3) if Andrx exercised its option to acquire a license from HMR, the date the license agreement became effective.

[4] HMR and Andrx stipulated that, for the purposes of the Agreement, Andrx would have realized $100 million per year in profits from the sale of its generic product after receiving FDA approval.

mination that did not determine the issues of the patent's validity, enforcement, or infringement, and HMR failed to refile its patent infringement action.[5] HMR also agreed that it would not seek preliminary injunctive relief in the ongoing patent infringement litigation.[6]

On July 8, 1998, the statutory thirty-month waiting period expired. On July 9, 1998, the FDA issued its final approval of Andrx's ANDA. Pursuant to the Agreement, HMR began making quarterly payments of $10 million to Andrx, and Andrx did not bring its generic product to market.

On September 11, 1998, Andrx, in a supplement to its previously filed ANDA, sought approval for a reformulated generic version of Cardizem CD. Andrx informed HMR that it had reformulated its product; it also urged HMR to reconsider its infringement claims. On February 3, 1999, Andrx certified to HMR that its reformulated product did not infringe the '584 patent.

On June 9, 1999, the FDA approved Andrx's reformulated product. That same day, HMR and Andrx entered into a stipulation settling the patent infringement case and terminating the Agreement. At the time of settlement, HMR paid Andrx a final sum of $50.7 million, bringing its total payments to $89.83 million. On June

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[5] HMR had to notify Andrx within thirty days of such a determination that it continued to believe that Andrx's generic version of the drug infringed its patent and that it intended to refile its patent infringement action.

[6] HMR also agreed that it would give Andrx copies of changes it proposed to the FDA regarding Cardizem CD's package insert and immediate container label, that it would notify Andrx of any labeling changes pending before or approved by the FDA, and that it would grant Andrx an irrevocable option to acquire a nonexclusive license to all intellectual property HMR owned or controlled that Andrx might need to market its product in the United States.

23, 1999, Andrx began to market its product under the trademark Cartia XT, and its 180-day period of marketing exclusivity began to run. Since its release, Cartia XT has sold for a much lower price than Cardizem CD and has captured a substantial portion of the market.

C. Procedural History

The first complaint challenging the legality of the Agreement was filed in August 1998, shortly after the FDA issued its final approval for Andrx's generic version of Cardizem CD. That complaint, and the other complaints that were subsequently filed, have been consolidated by the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, for coordinated or consolidated pretrial proceedings in the Eastern District of Michigan.[7] JA 56-58.

For all of the plaintiffs, the foundation for their claims is the allegation that but for the Agreement, specifically the payment of $40 million per year, Andrx would have brought its generic product to market once it received FDA approval and at a lower price than the patented

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[7] As described by the district court, the plaintiffs fall into three groups: (1) the "State Law Plaintiffs," indirect purchasers, and class representatives, from various states whose complaints, initially filed in state court and then removed to federal district court by defendants, allege violations of state antitrust and consumer protection statutes, JA 908-1011; (2) the "Sherman Act Class Plaintiffs," direct purchasers, and class representatives, whose complaint, filed in federal district court, alleges a violation of federal antitrust law, JA 139-159; and (3) the "Individual Sherman Act Plaintiffs," two groups of purchasers, not representatives of any class, whose complaints, filed in federal district court, allege violations of federal antitrust law, JA 860-881 (filed by The Kroger Co., Albertson's, Inc., The Stop and Shop Supermarket Co., and Eckerd Corp.); JA 887-896 (filed by CVS Meridian, Inc. and Rite Aid Corp.). *See* Dist. Ct. Op. I, at 625-27. Each group has filed a brief on appeal.

Cardizem CD sold by HMR. They further allege that the Agreement protected HMR from competition from both Andrx and other potential generic competitors because Andrx's delayed market entry postponed the start of its 180-day exclusivity period, which it had agreed not to relinquish or transfer. The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs bring claims under the federal antitrust laws, specifically section 1 of the Sherman Act, 15 U.S.C. § 1; they seek treble damages under section 4 of the Clayton Act, 15 U.S.C. § 4. The State Law Class Plaintiffs bring claims under various state antitrust laws.[8]

The defendants, HMR and Andrx, filed various motions to dismiss, all of which were denied. *See* Dist. Ct. Op. I, at 624. Of relevance to the present appeal, the defendants argued that all of the plaintiffs had failed to allege and could not allege an "antitrust injury" cognizable under section 1 of the Sherman Act or under the respective state antitrust statutes. *Id.* at 645. The district court concluded that the plaintiffs had adequately alleged "antitrust injury." *Id.* at 645-58. In reaching its conclusion, the district court first considered whether the plaintiffs' allegations satisfied the test articulated by the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). In *Brunswick*, the Supreme Court defined "antitrust injury" as "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 429 U.S. at 489. The district court explained its conclusion that the plaintiffs satisfied this test as follows:

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[8] Of the State Law Plaintiffs, the plaintiffs from seven states (California, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin) and the District of Columbia claim violations of state antitrust law. Dist. Ct. Op. I, at 625 n.3.

> As to the first prong of the antitrust injury test, the Supreme Court has observed that "[t]he Sherman Act was enacted to assure our customers the benefits of price competition, and our prior cases have emphasized the central interest in protecting the economic freedom of participants in the relevant market." *Associated General*, 459 U.S. at 538. Plaintiffs are customers, not competitors of Defendants, and the injury claimed consists of higher prices paid for drugs as a result of the contractually mandated absence of competition between HMRI and Andrx. As to the second, or causal connection prong of the antitrust injury test, Plaintiffs have alleged that the HMRI/Andrx Agreement decreased generic competition, and that the decreased competition bargained for in the HMRI/Andrx Agreement caused their injuries. Thus, Plaintiffs' injuries coincide precisely with the rationale for finding a violation of the antitrust laws in the first place. Since the very purpose of antitrust law is to ensure that the benefits of competition flow to purchasers of goods affected by the violation, "buyers have usually been preferred plaintiffs in private antitrust litigation," and a purchaser's standing "to recover for an overcharge paid directly to an illegal cartel or monopoly is seldom doubted." 2 P. Areeda & H. Hovemkamp, supra, ¶ 370[,] at 253. Plaintiffs have sufficiently pled facts that show they satisfy the "antitrust injury" test set forth in *Brunswick*.

Dist. Ct. Op. I, at 650-51. The district court then considered whether the Sixth Circuit's decisions in *Axis, S.p.A. v. Micafil*, 870 F.2d 1105 (6th Cir. 1989), *Hodges v. WSM, Inc.*, 26 F.3d 36 (6th Cir. 1994), and *Valley Products Co. v. Landmark*, 128 F.3d 398 (6th Cir. 1997) required a different conclusion, Dist. Ct. Op. I, at 651-

57, particularly the statement in *Hodges* that "because plaintiffs did not allege, nor could they that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case." 26 F.3d at 39 (emphasis added). After closely examining the facts and holdings of those cases, it rejected the defendants' contention that the Sixth Circuit's "necessary predicate" test meant that an antitrust complaint should be dismissed "simply because the defendant can conjure up a set of facts, contradicting those alleged in the plaintiff's complaint, but supporting an alternative possible cause for Plaintiffs' injuries that would not offend the antitrust laws." Dist. Ct. Op. I, at 651. It explained further:

> While the Sixth Circuit language found in the last paragraph of *Hodges* and repeated in *Valley Products* appears to broadly apply to the facts presented here, careful examination of these decisions reveals otherwise. The quoted language goes well beyond the antitrust injury test announced in *Brunswick*, goes well beyond what the Sixth Circuit actually did in each of these cases, goes further than the underlying facts allow, and is mutually inconsistent with the material cause standard that is to be applied in antitrust cases.

Id. at 652. Accordingly, the district court denied the defendants' motions to dismiss for failure to allege antitrust injury.

The plaintiffs then moved for partial summary judgment on the issue of whether the Agreement was a *per se* illegal restraint of trade. The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market

with its generic version of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal. Dist. Ct. Op. II, at 705-06.

Pursuant to 28 U.S.C. § 1292(b), the district court certified for interlocutory appeal the two questions quoted above.[9]

II. DISCUSSION

As we believe that our answer to the second question sheds light on our consideration of the first, we address first whether the Agreement was a *per se* illegal restraint of trade before considering whether the plaintiffs adequately alleged antitrust injury.

A. *Per Se* Illegal Restraint of Trade

We review *de novo* the district court's ruling on summary judgment that the Agreement was a *per se* illegal restraint of trade. *Holloway v. Brush*, 220 F.3d 767, 772 (6th Cir. 2000). Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

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[9] Since oral argument before this Court, the defendants have reached a settlement with the Sherman Act Class Plaintiffs. A settlement with the State Law Plaintiffs and the State Attorneys' General is subject for a final approval hearing before the District Court in October 2003. The Sherman Act Individual Plaintiffs have settled with HMR (now Aventis Pharmaceuticals), but have not settled with Andrx. The defendants have represented to the Court that these settlements have not mooted the certified issues presented by this appeal. *See* Letter to U.S. Court of Appeals for the Sixth Circuit, filed Feb. 20, 2003.

1. Relevant Antitrust Law

Section 1 of the Sherman Act[10] provides that "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . ." 15 U.S.C. § 1. Read "literally," section 1 "prohibits *every* agreement in restraint of trade." *Arizona v. Maricopa Cty. Medical Soc.*, 457 U.S. 332, 342 (1982). However, the Supreme Court has long recognized that Congress intended to outlaw only "unreasonable" restraints. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *Maricopa Cty.*, 457 U.S. at 342-43 (citing *United States v. Joint Traffic Ass'n*, 171 U.S. 505 (1898)). Most restraints are evaluated using a "rule of reason." *State Oil*, 522 U.S. at 10. Under this approach, the "finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* (citing *Maricopa Cty.*, 457 U.S. at 343 & n.13).

Other restraints, however, "are deemed unlawful *per se*" because they "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.* (citing *Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)). "*Per se* treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.' " *Id.* (quoting *Maricopa Cty.*, 457 U.S. at 344); *see also*

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[10] It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive. *See* State Law Pls. Br. at 41-44.

Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979) (a *per se* rule is applied when "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output."). The *per se* approach thus applies a "conclusive presumption" of illegality to certain types of agreements, *Maricopa Cty.*, 457 U.S. at 344; where it applies, no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition.[11] *National College Athletic Ass'n ("NCAA") v. Board of Regents*, 468 U.S. 85, 100 (1984). As explained by the Supreme Court, "[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive consequences. Cases that do not fit the generalization may arise, but a *per se* rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 n.6 (1977).

The Supreme Court has identified certain types of restraints as subject to the *per se* rule. The classic examples are naked, horizontal restraints pertaining to prices or territories. *See, e.g., NCAA*, 468 U.S. at 100 ("Hori-

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[11] The risk that the application of a *per se* rule will lead to the condemnation of an agreement that a rule of reason analysis would permit has been recognized and tolerated as a necessary cost of this approach. *See, e.g., Maricopa Cty.*, 457 U.S. at 344 ("As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a fullblown inquiry might have proved to be reasonable."); *United States v. Topco Associates, Inc.*, 405 U.S. 596, 609 (1972) ("Whether or not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.").

zontal price fixing and output limitation are ordinarily condemned as a matter of law under an 'illegal *per se*' approach because the probability that these practices are anticompetitive is so high."); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."); *United States v. Topco Assocs.*, 405 U.S. 596, 608 (1972) ("One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, *e.g.*, manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that horizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition. Such limitations are *per se* violations of the Sherman Act." (internal citations omitted)); *Northern Pacific Ry.*, 356 U.S. at 5 ("Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements." (internal citations omitted)).

2. Application

In answering the question whether the Agreement here was *per se* illegal, the following facts are undisputed and dispositive. The Agreement guaranteed to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it

had obtained FDA approval, protecting HMR's exclusive access to the market for Cardizem CD throughout the United States until the occurrence of one of the end dates contemplated by the Agreement. (In fact, Andrx and HMR terminated the Agreement and the payments in June 1999, before any of the specified end dates occurred.) In the interim, however, from July 1998 through June 1999, Andrx kept its generic product off the market and HMR paid Andrx $89.83 million. By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer.[12] There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

None of the defendants' attempts to avoid *per se* treatment is persuasive. As explained in greater detail in the

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[12] As the district court for the Eastern District of New York recently observed, in distinguishing the district court's opinion in the present case (*Cardizem II*),

> By agreeing both not to end the underlying patent dispute and not to market a generic drug product in the relevant domestic market, Andrx . . . effectively precluded or seriously delayed both the [patent] court decision and the commercial marketing trigger of the 180-day exclusivity period. As a result, any future [generic] filers were delayed in coming to market . . . .

In re Ciprofloxacin Hydrochloride Antitrust Litigation, MDL No. 1383, 2003 WL 21146562, at *46 (E.D.N.Y. May 20, 2003); *see also In re Tamoxifen Citrate Antitrust Litigation*, MDL No. 1408, 2003 WL 21196817, at *9 (E.D.N.Y. May 13, 2003).

district court's opinion, *see* Dist. Ct. Op. II, at 700-705, the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation. As the plaintiffs point out, it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness[13] in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market. Individual Sherman Act Plaintiffs Br. at 26-30. Nor does the fact that this is a "novel" area of law preclude *per se* treatment, *see Maricopa Cty.*, 457 U.S. at 349. To the contrary, the Supreme Court has held that " '[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.' " *Id.* at 349 (quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222 (1940)). We see no reason not to apply that rule here, especially when the record does not support the defendants' claim that the district court made "errors" in its analysis.[14] Finally, the

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[13] As the court in *In re Ciprofloxacin* observed,

> [w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.

2003 WL 21146562, at *46.

[14] For example, the defendants charge that the district court erred in concluding that in the absence of the Agreement, Andrx *would* have marketed its generic product before the end of the patent litigation (once it had received FDA approval). However, the district court never held that Andrx *would* have launched the original formulation of its generic while the patent suit was pending, only that

defendants' claims that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. *See, e.g., Maricopa Cty.*, 457 U.S. at 351. To reiterate, the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case. As the Supreme Court explained in *Maricopa County*:

> The respondents' principal argument is that the *per se* rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the *per se* concept. The anticompetitive potential inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application.

457 U.S. at 351. Thus, the law is clear that once it is decided that a restraint is subject to *per se* analysis, the claimed lack of any actual anticompetitive effects or

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it *could* have. The defendants also contend that the district court erred in assuming that Andrx could have marketed its *reformulated* generic, which only received FDA approval in June 1999, before it did, but the district court made no such assumption. Finally, the defendants argue that the district court erred in reaching the conclusion that Andrx and HMRI were horizontal competitors. They maintain that it would be inconsistent with Hatch-Waxman scheme to allow a court to treat a generic manufacturer who is seeking FDA approval and has been charged with patent infringement and the patent holder as horizontal competitors. Hatch-Waxman notwithstanding, the defendants are potential rivals in the market for Cardizem CD; an agreement between them is thus an agreement between horizontal competitors.

presence of procompetitive effects is irrelevant. Of course, our holding here does not resolve the issues of causation and damages, both of which will have to be proved before the plaintiffs can succeed on their claim for treble damages under the Clayton Act.

B. Antitrust Injury

We now consider whether the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an "antitrust injury."[15] A district court's denial of a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) is subject to *de novo* review. *Ziegler v. IBP Hog Market, Inc.*, 249 F.3d 509, 511-12 (6th Cir. 2001). In deciding a motion to dismiss, we, like the district court, "must construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claim that would entitle him to relief." *Id.* at 512. "When an allegation is capable of more than one inference, it must be construed in the plaintiff's favor." *Helwig v. Vencor*, Inc., 251 F.3d 540, 553 (6th Cir. 2001) (internal citations omitted), *cert. dismissed*, 536 U.S. 935 (2002).

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[15] Our conclusion that the Agreement was a *per se* illegal restraint of trade does not obviate the need to decide whether the plaintiffs adequately alleged antitrust injury. *See Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 341-42 (1990) ("The *per se* rule is a method of determining whether § 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages under § 4 of the Clayton Act.").

1. Relevant Antitrust Law

A private antitrust plaintiff, in addition to having to show injury-in-fact and proximate cause, must allege, and eventually prove, "antitrust injury." *Brunswick*, 429 U.S. at 489. "Antitrust injury" is (1) "injury of the type the antitrust laws were intended to prevent" and (2) injury "that flows from that which makes defendants' acts unlawful." *Id.* As explained by the Supreme Court in *Brunswick*, the antitrust injury doctrine is designed to ensure that "the injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Id.* The Supreme Court has further explained the requirement as "ensur[ing] that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place," and, more specifically, it "ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." *Atlantic Richfield Co. v. USA Petroleum Co.* 495 U.S. 328, 342-343 (1990).

2. Plaintiffs' Allegations

In the present case, the plaintiffs' critical allegations include the following: (1) Andrx had developed and was ready to market a generic version of Cardizem CD; (2) Andrx had certified to the FDA that its generic product did not infringe any of the patents associated with Cardizem CD; (3) the patent infringement litigation was a "sham"[16]; (4) prior to entering into the Agreement,

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[16] The State Law Plaintiffs allege that the '584 patent "represented no substantive change or improvement to Cardizem CD but rather was prosecuted and listed solely to give HMR a basis for initiating sham patent infringement litigation to delay and exclude Andrx's generic Cardizem CD from the Cardizem CD market for at least 30 months." JA 948, ¶ 101. They further allege that Andrx's

Andrx had represented to the federal district court presiding over the patent infringement litigation that it intended to market and sell its generic version of Cardizem CD as soon as it received final FDA approval; (5) the Agreement entered into by Andrx and HMR provided, among other things, that once the FDA approved Andrx's ANDA, HMR would commence making quarterly payments of $10 million in exchange for Andrx not bringing its generic product to market; (6) Andrx did not enter the market upon receiving FDA approval on July 9, 1998; (7) pursuant to the Agreement, HMR ultimately paid Andrx $89.83 million; (8) "but for" the Agreement and the payment, Andrx would have begun to market its generic version of Cardizem CD on or shortly after July 9, 1998; (9) the Agreement effectively eliminated generic competition in the market for Cardizem CD from July 1998 through July 1999, when the Agreement was terminated; and (10) due to the lack of a competitive market, the plaintiffs were deprived of the option of purchasing a generic lower-priced drug and paid more than they otherwise would have for Cardizem CD. JA 908-1011 (State Law Pls. Compl.); JA 139-159 (Sherman Act Class Pls. Compl.); JA 848-859, 860-881, 887-896 (Individual Sherman Act Pls. Compls.); *see also* Dist. Ct. Op. I, at 647.

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specified dissolution profile, submitted to the FDA after the patent infringement litigation was filed, was "clearly distinct" from the '584 patent, JA 949, ¶ 103, and that HMR continued its pursuit of the patent infringement litigation "despite the absence of any reasonable belief that their claim would be held to be valid upon adjudication," *id.* ¶ 104. Finally, they allege that HMR's "goal and intention in pursuing [the patent infringement litigation] was solely to indefinitely delay and prevent the entry of Andrx's product into the marketplace and invoke the automatic 30-month administrative delay in the FDA approval process." *Id.*; *see also* JA 154, ¶ 53 (amended complaint of Sherman Act Class Plaintiffs alleging that "patent litigation" was "sham[ ]")).

3. Application of *Brunswick*

The plaintiffs' allegations fall easily within the two critical *Brunswick* categories. It is clear, and not disputed on appeal, that the plaintiffs have alleged the "type of injury" the antitrust laws were meant to prevent. The plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint. Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890. *See Associated Gen. Contractors v. California State Council*, 459 U.S. 519, 538 (1983).

There remains the issue of whether the alleged injury "flows" from that "which makes defendants' acts unlawful," i.e., its anticompetitive effects. The facts of *Brunswick* shed light on the meaning and purpose of this requirement. In *Brunswick*, a bowling alley owner claimed that another competitor's takeover of two failing bowling alleys was an illegal merger. The plaintiff alleged that it was injured by the merger because if the other bowling alleys had simply gone out of business, it would have increased its sales in the bowling alley market. What would have made the acquisition unlawful for antitrust purposes, however, was the risk that increased concentration in the bowling alley market would reduce future competition and cause prices to rise. The plaintiff's injury, on the other hand, flowed from the more immediate competition-enhancing effects of the merger; not its future potential to reduce competition. Accordingly, there was no antitrust injury because the plaintiff's injury did not "flow" from the anticompetitive effects of the alleged antitrust violation.

In the present case, the facts are much more straightforward. As explained above, the alleged antitrust violation, HMR's agreement to pay Andrx $40 million per year not to bring its generic product to market and compete with Cardizem CD, is a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers. Unlike in *Brunswick*, here there is no question that the alleged injury—paying higher prices for a product due to a lack of competition in the market—is the type of injury that can, and the plaintiffs have alleged did, flow from the anticompetitive effects of the Agreement (a horizontal market allocation agreement). Under these circumstances, dismissal would be appropriate only if the plaintiffs' allegations, taken as true and construed in their favor, somehow precluded the possibility that their injury flowed from the anticompetitive effects of the Agreement and payment. No such conclusion can be reached in this case. To the contrary, the complaint clearly alleges that but for the Agreement, specifically the payment of $40 million per year, the plaintiffs would not have suffered their injury; there is nothing in the complaint that belies this allegation or justifies this Court not accepting it as true. The defendants' argument to the contrary, that Andrx would not have entered the market even if there had been no Agreement and payment because of its fear of damages in the patent infringement litigation, creates a disputed issue of fact, not appropriately resolved on a motion to dismiss. Indeed, a trier of fact may well find that the $89 million payment renders incredible the defendants' claim that Andrx would have refrained from marketing simply because of its fear of infringement damages.

4. "Necessary Predicate" Test

We turn now to the defendants' contention, and the reason for this certified appeal, that the Sixth Circuit's "necessary predicate" test requires more than *Brunswick* and leads to a different conclusion.[17] The defendants' argument arises out of a statement made in this Court's decision in *Hodges*. In that case, after having decided to affirm the district court's dismissal for failure to allege

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[17] It is noteworthy that the district court has responsibility for these cases by assignment of the Judicial Panel on Multidistrict Litigation, and we address this certified question in aid of the district court. This consolidated proceeding includes cases that were originally filed in various state and federal courts, raising state and federal antitrust claims. The state cases were first removed to federal district court and then transferred to the Eastern District of Michigan. In considering the issue of antitrust injury, the district court applied the same analysis, including the application of Sixth Circuit precedent, to all of the antitrust claims. *Id.* at 645-58. As no party has taken issue with this approach, either before the district court or on appeal, we have followed the same path. We note, however, that although it is clear and undisputed that the state antitrust laws at issue all "either follow federal Sherman Act precedent or find federal case law persuasive," Dist. Ct. Op. II, at 692 & n.6 (citing state cases); *see also* State Law Pls. Br. at 41-15, and that in a federal multidistrict litigation there is a preference for applying the law of the transferee district, *see In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993), it is not clear that precedent "unique" to a particular circuit and arguably divergent from the predominant interpretation of a federal law, such as the Sixth Circuit's "necessary predicate" gloss on the antitrust injury doctrine, should be applied to state antitrust laws or federal antitrust claims that originated in other circuits, *see In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171 (2d Cir. 1987), *aff'd*, 490 U.S. 122 (1989) (law of transferor forum on federal question merits close consideration, but does not have *stare decisis* effect). As we agree with the district court that the plaintiffs have alleged antitrust injury as contemplated by the Sixth Circuit, this consideration is of academic interest only. Were the outcome otherwise, it might require further consideration.

antitrust injury, the Court stated: "[b]ecause plaintiffs did not allege, nor could they, that the illegal antitrust conduct was a necessary predicate to their injury *or* that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case pursuant to Federal Rule of Civil Procedure 12(b)(6)." *Hodges*, 26 F.3d at 39 (emphasis added).

The defendants contend that this statement means that in order to allege antitrust injury adequately, a plaintiff must allege that the only way the defendant *could* have caused the plaintiff's injury was by engaging in the antitrust violation. Defs. Br. at 32-33. In other words, if the defendant could have in theory caused the same injury without engaging in an antitrust violation, the plaintiff has not suffered an "antitrust injury," even if in fact it was the antitrust violation that caused the actual injury in a particular case. Applied to the present case, the defendants contend that the plaintiffs cannot allege an antitrust injury because Andrx *could* have unilaterally (and legally) decided not to market its generic version of Cardizem CD; they contend it is immaterial whether, in fact, it was the Agreement and the payment of $40 million per year that caused them to do so. *Id.*

We disagree.

First, simply looking at the actual language of the statement suggests that the defendants have conflated two ideas. What the court in *Hodges* said was that in order to survive a motion to dismiss for failure to allege antitrust injury, a plaintiff must allege *either*: (1) that the antitrust violation was "a necessary predicate" to their injury; *or* (2) that the defendants could injure plaintiffs only by engaging in the antitrust violation. 26 F.3d at 39. The defendants' interpretation conflates these options, effectively requiring plaintiffs to satisfy the second one even if they have already satisfied the first.

Second, nothing in the facts or holding of *Axis*, *Hodges*, or *Valley Products*, the cases relied upon by the defendants, supports their interpretation. Although it does not use the "necessary predicate" language, we consider first the Sixth Circuit's decision in *Axis*, the starting point for this line of antitrust injury cases.

In *Axis*, 870 F.2d 1105, the plaintiff was a foreign manufacturer of armature winding machines which sought to enter the United States market. After another foreign manufacturer purchased two American manufacturers, the plaintiff filed an antitrust suit against the purchaser claiming that the purchase was illegal because it reduced competition in the armature winding machine market. The plaintiff's alleged injury was its exclusion from the United States market. However, the plaintiff also alleged that it could not enter the market because it lacked access to indisputably valid and essential patents controlled by the defendant; the plaintiff did not challenge the legal right of the patent-holder to refuse to grant it a license. Nor did it or anyone else challenge the validity of the patents. We affirmed dismissal of the complaint because it failed to allege antitrust injury, noting that the "the anticompetitive act of purchasing [the American manufacturer] did not cause the plaintiff's alleged injury. The patents were an *impenetrable* barrier to the plaintiff's entry before [the defendant] purchased [the American manufacturer], and they remained as great a barrier afterwards." 870 F.2d at 1107 (emphasis added).

In *Hodges*, 26 F.3d 39, the plaintiff was an airport shuttle and tour bus operator who wanted to participate in the market for shuttle services from the Nashville airport to Opryland, an amusement park, hotel and convention center. It filed an antitrust suit against the companies that owned the Opryland site and operated the Grand Old Opry music radio program, as well as a sight-

seeing and tour company known as Grand Old Opry tours. The complaint alleged that those defendants had reached an illegal market division agreement with other shuttle and tour bus operators that the competitors would refrain from transporting passengers from the airport to the Opryland complex, leaving the airport shuttle market to the defendants themselves. In exchange, the defendants would hire vans and buses from their former competitors for Opryland's sightseeing tour business. The plaintiff's alleged injury was its exclusion from the airport to Opryland shuttle market. The plaintiff further alleged that the defendants policed their illegal agreement by refusing the plaintiff, and any other non-conspiring shuttle service companies, access to the Opryland property; the plaintiff did not challenge the defendants' lawful right to exclude it from their private property. The case was dismissed for failure to allege antitrust injury.

In *Valley Products*, 128 F.3d 398, the plaintiff was a manufacturer of logo-bearing hotel soaps and other hotel amenities which wanted to supply its products to franchisees of a certain hotel franchisor. The hotel franchisor authorized certain vendors to use its trademark on products, which the franchisees would then purchase. After the plaintiff's vendor agreement was terminated, it filed an antitrust suit against the hotel franchisor and its two remaining authorized vendors, the plaintiff's competitors, alleging that their arrangement was an attempt to impose an illegal tying arrangement on franchisees (by conditioning the franchise agreement on the purchase of logoed amenities from the two preferred vendors). There was no allegation that the vendors and the franchisor had agreed to exclude the plaintiff. The plaintiff's alleged injury was its exclusion from the logoed amenity market for the defendant franchisor's franchisees. The case was

dismissed for failure to allege antitrust injury. On appeal, we observed that the Sixth Circuit "has been reasonably aggressive in using the antitrust injury doctrine to bar recovery where the asserted injury, although linked to an alleged violation of the antitrust laws, flows directly from conduct that is not itself an antitrust violation." *Valley Products*, 128 F.3d at 403.

As the above discussion of *Axis*, *Hodges* and *Valley Products* demonstrates, the facts and holdings of those cases provide no support for the defendants' proposed interpretation of the "necessary predicate" language in *Hodges*. In none of these cases was a complaint dismissed for failure to allege antitrust injury based on a defendant's claim that it *could* have caused the same injury without committing the alleged violation. Rather, the complaints were dismissed for failure to allege antitrust injury because each of the defendants had taken an action that it was lawfully entitled to take, independent of the alleged antitrust violation, which was the actual, indisputable, and sole cause of the plaintiff's injury. In *Axis*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the armature winding machine market—admittedly flowed not from the anticompetitive effects of the allegedly illegal purchase, but from its lack of access to "impenetrable" patents. 870 F.2d at 1107. In *Hodges*, the antitrust violation was not the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the shuttle services from the airport to the Opryland site owned by defendants—actually flowed not from the anticompetitive effects of an allegedly unlawful market division agreement, but from the defendants' "lawful refusal to grant plaintiffs access to their private property." 26 F.3d at 39. In *Valley Products*, the antitrust violation was not

the "necessary predicate" because the plaintiff's alleged injury—its exclusion from competing in the franchisor's logoed amenity market—actually flowed, not from the anticompetitive effects of an allegedly unlawful tying arrangement, but from the defendant's lawful termination of a vendor agreement.[18] Thus, in reality, we have only dismissed a case for failure to allege that an antitrust violation is the "necessary predicate" for the plaintiff's injury where it has been apparent from the face of the complaint that actual and unequivocally legal action by the defendant would have caused plaintiff's injury, even if there had been no antitrust violation.

Application to this case of the "necessary predicate" test, as we have applied it in the cases which are the subject of the certified question, demonstrates that the district court correctly refused to dismiss these complaints for failure to allege antitrust injury. In essence, as exposed by the *per se* analysis above, *see supra* Part II.A., the complaints allege a plain vanilla horizontal agreement to restrain trade in the form of a multi-million dollar cash payment in consideration for forbearance by Andrx from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for the patented product. There is nothing on the face of the complaint that suggests, much less establishes as a matter of law, that there was any physical or "impenetrable" legal impediment to Andrx's production and sale of its FDA-approved generic product. Indeed, some plaintiffs allege that HMR's patent infringement suit against Andrx was a "sham." JA 948, ¶ 101; JA 949,

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[18] This court's decision in *Watkins & Son Pet Supplies v. Iams Co.*, 254 F.3d 607 (6th Cir. 2001), similarly found no antitrust injury where the plaintiff's alleged injury—its exclusion from the market—flowed from the termination of its distributorship, not from the defendants' allegedly illegal distribution restraints.

¶¶ 103-04; JA 154, ¶ 53. Nor can the defendants identify a lawful right that they had and exercised and that indisputably caused plaintiffs' injury. Thus, the complaint may be fairly construed as alleging that the *per se* illegal Agreement with its $89 million payment, not HMR"s disputed 45%-18 patent, constituted the "necessary predicate" for Andrx's decision to keep its FDA-approved 55%-18 generic product off the market and HMR free from *any* generic product competition. The fact that Andrx could have unilaterally, and legally, decided not to bring its generic product to a manifestly profitable market has no relevance in assessing whether the plaintiffs adequately alleged that the antitrust violation was the necessary predicate for their injury.[19]

What remains is the defendants' contention that Andrx would have stayed out of the market even absent the Agreement and the payment of $40 million per year because Andrx feared incurring damages in the patent infringement litigation. Proof of allegations on the face of this complaint and reasonable inferences therefrom, however, could persuade a trier of fact that had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished. Under the aegis of the complaint and inferences, a fact trier could also find that even if it is a "prudent" industry practice for a generic manufacturer to stay out of the market until

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[19] In addition, the defendants' position, if adopted, risks undermining a basic premise of antitrust law that, as the district court observed, in many instances, an otherwise legal action—*e.g.* setting a price—becomes illegal if it is pursuant to an agreement with a competitor. Under the defendants' view, such an action would never cause antitrust injury because a defendant *could* have unilaterally and legally set the same price.

the resolution of patent infringement litigation, Defs. Br. at 33, in this case, the patent infringement suit was a "paper tiger" incapable of deterring the generic producer from entering the market as soon as the FDA approved its product—as it had formally advised the patent court. If proved to be true, it would almost necessarily follow that the plaintiffs' injury flowed from the Agreement and payment of $40 million per year. At this stage of the litigation, we must leave this dispute for the trier of fact to evaluate.

III. CONCLUSION

For the foregoing reasons, we answer both of the district court's certified questions as follows: it properly resolved the questions that it put to us in the course of denying defendants' motions to dismiss and granting the plaintiffs' motions for summary judgment that the defendants had committed a per se violation of the antitrust laws.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Master File No. 99-md-1278
MDL No. 1278

Honorable Nancy G. Edmunds

IN RE: CARDIZEM CD ANTITRUST LITIGATION.

THIS DOCUMENT RELATES TO:
ALL ACTIONS,

ORDER NO. 13

MEMORANDUM OPINION AND ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

State Law Plaintiffs and Sherman Act Plaintiffs[1] are before the Court on motions, brought pursuant to Fed. R.

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[1] The Sherman Act Plaintiffs include all Plaintiffs in the Sherman Act class cases and the Sherman Act individual cases consolidated in this Court, Case Nos. 99-73870, 99-73259, 99-73735, and 99-75036.

Civ. Pro. 56(a), for partial summary judgment. Plaintiffs' motions raise a single issue, whether Defendants' September 24, 1997 Agreement ("HMRI/Andrx Agreement") constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the various state antitrust laws at issue here. This Court answers this question in the affirmative. It concludes that the HMRI/Andrx Agreement is an agreement between horizontal competitors that allocates the entire United States market for Cardizem CD and its bioequivalents to Defendant HMRI, and thus constitutes a restraint of trade that has long been held illegal *per se* under established Supreme Court precedent. *See Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *United States v. Topco Associates, Inc.*, 405 U.S. 596 (1972); *United States v. Cooperative Theatres of Ohio, Inc.*, 845 F.2d 1367 (6th Cir. 1988). Accordingly, Plaintiffs' motions for partial summary judgment are **GRANTED**.

I. Facts

A. Relevant Statutory and Regulatory Framework

The manufacture and distribution of pharmaceutical drugs are regulated by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. (1994). Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding that the Act's "cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D. D.C. 2000). The Hatch-Waxman Amendments, 21 U.S.C § 355 (1994), embody Congress' intent "to make available more low cost generic drugs" and its attempt "to balance

two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Id.* (internal quotes and citations omitted).

"[T]he Hatch-Waxman Amendments established new guidelines for the approval of generic drugs. Generic drug makers were permitted to file an Abbreviated New Drug Application ("ANDA") which incorporated data that the 'pioneer' manufacturer had already submitted to the FDA regarding the pioneer drug's safety and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is 'bioequivalent' to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv). As protection for pioneer drug makers, the applicant is also required to certify in one of four ways that the generic drug will not infringe on any patent which claims the pioneer drug. *See id.* at § 355(j)(2)(A)(vii)." *Mylan Pharm.*, 81 F. Supp. 2d at 32.

Applicable here is the fourth type of certification. Paragraph IV certification "permits the applicant to allege that the patent for the pioneer drug is either invalid or will not be infringed by the marketing of the generic drug. See id. at § 355(j)(2)(A)(vii)(IV)." *Mylan Pharm.*, 81 F. Supp. 2d at 32. As the District Court for the District of Columbia recently observed, "[a] generic drug manufacturer's filing of a so-called 'Paragraph IV' certification has important legal ramifications. It automatically creates a cause of action for patent infringement. Upon receiving notice of a Paragraph IV certification's filing, the patent holder or pioneer manufacturer has 45 days within which to file suit against the generic manufacturer. *See id.* at § 355(j)(5)(B)(iii). If such an action is brought, the FDA cannot approve the

generic manufacturer's ANDA for 30 months. *See id.* However, if the court hearing the infringement action rules before the expiration of the 30-month period that the patent at issue is 'invalid or not infringed,' then 'the approval shall be made effective on the date of the court decision[.]' *Id.* at § 355(j)(5)(B)(iii)(I)." *Mylan Pharm.*, 81 F. Supp. 2d at 32-33.

To encourage competitors to bring cheaper generic drugs to market, and acknowledging that they will likely incur "potentially substantial litigation costs associated with challenging pioneer drug makers' patents, the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications. The first generic manufacturer to file an ANDA containing a Paragraph IV certification with respect to a specific patent is awarded a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent. In other words, no other ANDA for the same generic drug product will be approved during those 180 days." *Id.* at 33.

Section 355(j)(5)(B)(iv) provides that:

> If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is

> the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

Id. (quoting 21 U.S.C. § 355(j)(5)(B)(iv)). Accordingly, the 180-day period of exclusivity "can be triggered in one of two ways-either (1) when the generic producer begins commercial marketing of its drug (the 'commercial marketing trigger'), or (2) when there is a court decision finding the pioneer drug maker's patent invalid or not infringed (the 'court-decision trigger')." *Mylan Pharm.*, 81 F. Supp. 2d at 33 (footnote omitted).

B. Andrx's ANDA, the HMRI/Andrx Patent Suit, ANDA Supplements, and the September 1997 HMRI/Andrx Agreement

Prior to August 1995, Defendant Andrx had been developing its own generic version of Cardizem CD, and provided samples of its proposed generic substitute for Cardizem CD to the Hoechst Defendants so they could perform their own tests to confirm that there was no infringement of the patents claiming Cardizem CD and thus avoid litigation.

On September 22, 1995, Andrx filed its Abbreviated New Drug Application ("ANDA") No. 74-752 with the United States Food & Drug Administration ("FDA") seeking approval to manufacture and sell a generic form of Cardizem CD, a once-daily, controlled release dosage of the chemical compound diltiazem hydrochloride, manufactured and sold by Defendant HMRI.

On November 28, 1995, two months after Andrx filed its ANDA, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,470,584 ("the '584 patent") to Carderm which then licensed it to HMRI. The '584 patent claims a delayed release diltiazem formulation with an

in-vitro dissolution profile where from 0-45% of total diltiazem is released after 18 hours and not less than 45% of total diltiazem is released after 24 hours.

On December 31, 1995, Andrx made a Paragraph IV Certification with regard to all unexpired patents listed in the FDA's Orange Book[2] allegedly claiming Cardizem CD and certified to HMRI that the product reflected in its ANDA did not infringe the patents owned or controlled by HMRI or its affiliates, including the '584 patent.

On January 31, 1996, HMRI and Carderm filed a patent infringement suit against Andrx in the District Court for the Southern District of Florida ("HMRI/Andrx patent case"). The filing of the suit triggered the 30-month Hatch-Waxman waiting period, which expired on or before July 8, 1998. Thus, Andrx's ANDA could not be finally approved and it could not begin commercial marketing of its generic version of Cardizem CD until the 30-month waiting period expired or the court hearing the infringement action ruled that the patent at issue was invalid or not infringed, whichever first occurred. *See Mylan Pharm.*, 81 F. Supp. 2d at 32-33.

On April 4, 1996, Andrx filed an amendment to its ANDA No. 74-752, amending the dissolution profile to provide that not less than 55% of the total diltiazem was to be released after 18 hours. HMRI was notified of this change but continued to prosecute its infringement claims against Andrx.

On September 15, 1997, the FDA issued its tentative approval of Andrx's ANDA, which was an indication

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[2] A list of patents believed to be covered by a pioneer drug product or its use must be submitted to the FDA, and the patents are listed in a publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

that the ANDA would be approved as soon as it was legally eligible; i.e., on July 8, 1998, the date the 30 month Hatch-Waxman waiting period was due to expire, or earlier if the court presiding over the HMRI/Andrx patent infringement action ruled that the '584 patent was invalid or not infringed.

Less than ten days later, on September 24, 1997, HMRI and Andrx entered into the HMRI/Andrx Agreement. It is this Agreement that Plaintiffs assert constitutes a per se violation of § 1 of the Sherman Act.

By July 9, 1998, the FDA had granted final approval of Andrx's ANDA for a generic version of Cardizem CD, the 30 month Hatch-Waxman waiting period had expired, and Andrx was no longer restricted under the Hatch-Waxman Amendments from immediately marketing and selling its generic drug.[3] Under the terms of the HMRI/Andrx Agreement, however, Andrx had agreed not to enter the market with its generic version of Cardizem CD, and on July 9, 1998, HMRI's obligation to begin making quarterly payments of $10 million to Andrx was triggered.

Two months later, on September 11, 1998, Andrx filed a prior approval supplement to its ANDA No. 74-752 seeking to once again change the dissolution profile of its generic drug. Specifically, Andrx sought permission to make the following change: "in addition to adding a small amount of a new ingredient to the SR2 bead coating, the Prior Approval Supplement submitted on September 11, 1998 requests permission to change the current 0.1 N HC1 dissolution specification for the SR2

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[3] The FDA's approval of Andrx's ANDA meant that FDA had found that the Andrx drug was "bioequivalent" to Cardizem CD and this in turn would make it possible, if not required, for pharmacists to fill prescriptions for Cardizem CD with Andrx's generic version of that drug. *See* Decl. of HMRI expert, A. Bennett, at ¶6.

bead *from 'not less than 55% of the total diltiazem released after 18 hours' to 'not less than 65% of the total diltiazem released after 18 hours'* ". *See* HMRI Appendix, Ex. 7 at 11 (emphasis added).

On October 7, 1998, Andrx informed HMRI that it had filed a prior approval supplement to its ANDA and urged HMRI to reconsider its infringement claims. *See* HMRI Appendix, Ex. 8, 6/9/99 Stipulation of settlement in HMRI/Andrx patent infringement action, ¶ 10; Bennett Decl. at ¶ 18; Bennett Decl., Ex. A at ¶ 15.

In January 1999, there was a flurry of activity. On January 8, 1999, HMRI wrote to Andrx suggesting that Andrx was required to file a new Para. IV certification, and on January 15, 1999, HMRI's counsel raised the same concerns with the FDA. *See* Bennett Decl. at ¶ 20. Then, on January 20 and 22, 1999, Andrx sent samples of its generic product with the new formulation to HMRI. *See* Bennett Decl., Ex. A at ¶¶ 19, 20.

On February 3, 1999, Andrx certified to HMRI that the reformulated product did not infringe the '584 patent. *See*. HMRI Appendix, June 9, 1999 Settlement Stip., Ex. 8 at ¶ 7. In its Second Supplemental Patent Certification ("Para. IV Certification"), Andrx asserted that the '584 patent would not be infringed by "the making, using or selling of the Andrx CARTIA XT because neither the Andrx CARTIA XT product nor any component of the Andrx CARTIA XT product exhibit an in-vitro dissolution profile that is the same as or equivalent to the in-vitro dissolution profile set forth in claims 1-9 of U.S. 5,470,584." HMRI Appendix, Ex. 7, Second Supplemental Patent Certification at 10.[4]

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[4] Andrx further explained that "[i]n addition to adding a small amount of a new ingredient to the SR2 bead coating, the Prior Approval Supplement submitted on September 11, 1998 requests permission to change the current 0.1 N HC1 dissolution specification for

Andrx further asserted that "the claims of U.S. 5,470,584 cannot be read to include the SR2 bead in Andrx's CARTIA XT product because of *statements made by Eli Shefter regarding the scope of the claims* of U.S. 5,470,584 in paragraph 13 of the Second Declaration Eli Shefter submitted in the lawsuit, *Hoechst Marion Roussel, et al. v. Andrx Pharmaceuticals, Inc.*, Civil Action No. 96-06121 CIV-Roettger (S.D. Fla.)." *Id.* at 13 (emphasis added). Andrx explained that it was providing "[a] more detailed discussion of this point" in a separate addendum to its Second Supplemental Notice, and also explained that the addendum was being provided "only to Carderm Capital L.P. and Hoechst Marion Roussel, Inc. because Carderm Capital L.P. is the owner of U.S. 5,470,584 and the NDA for Cardizem CD and because the addendum contains confidential information Andrx obtained from Carderm Capital L.P. and Hoechst Marion Roussel, Inc. in *Hoechst Marion Roussel et al. v. Andrx Pharmaceuticals, Inc.*, Civil Action No. 96-06121 CIV-Roettger (S.D. Fla.) that is subject to the terms of a Stipulated Protective Order." *Id.* at 13-14.

In its Confidential Addendum to its Second Supplemental Patent Certification, Andrx reiterated that "all SR2 or slower release beads in the Andrx CARTIA XT product will release not less than 65% of the total

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the SR2 bead from 'not less than 55% of the total diltiazem released after 18 hours' to 'not less than 65% of the total diltiazem released after 18 hours'. As clearly shown by the dissolution profiles attached hereto as Exhibit B, and more importantly the new 0.1 N HC1 dissolution specification of 'not less than 65% of the total diltiazem being released after 18 hours', neither the Andrx CARTIA XT product nor the individual SR1 beads and SR2 beads employed in the Andrx CARTIA XT product exhibit a dissolution profile that is within the three (3) specific dissolution ranges required by claims 1-9 of U.S. 5,470,584 and therefore cannot infringe any claim of U.S. 5,470,584." *Id.* at 11.

amount of diltiazem after 18 hours when tested according to the conditions recited in claim 1 of the '584 patent." HMRI Appendix, Ex. 7, Confidential Addendum to Andrx's Second Supplemental Patent Certification at 1. Andrx further explained that: "[t]his dissolution specification at the 18 hour point is more than 40% greater or 20 percentage points higher than the 45% maximum recited in claim 1 of the '584 patent." *Id.* Accordingly, Andrx asserted, "based upon arguments presented by HMR and HMR's expert, Dr. Shefter, in responding to Andrx's motions for summary judgment for non-infringement and invalidity in the *HMR v. Andrx* case, HMR cannot, in good faith, assert that SR2 beads which release 'not less than 65% of the total diltiazem after 18 hours' literally infringe claim 1 of the '584 patent" or infringe claim 1 under the doctrine of equivalents." *Id.* at 2-3. Specifically, Andrx asserted that: (1) in a 1/23/97 Eli Shefter Decl. at ¶ 38, Shefter had opined that he would consider the range of variability of the 18 hour dissolution measurement for these beads to be closer to 20% than 10%; (2) in a 1/23/97 Decl. at ¶ 42, Shefter had opined that "results ranging from 63 to 70% are not within the range of variability attributable to measurement limitations of the dissolution test"; (3) in a 3/7/97 Eli Shefter Decl., he had opined that "the error at 18 hours should be about + or - 10% or measured values of about 35% to 55% drug released"; (4) therefore "the scope of claim 1 of the '584 patent is limited to a maximum amount of 55% of diltiazem released after 18 hours"; and (5) accordingly, "SR2 beads that will release not less than 65% of diltiazem after 18 hours are clearly outside the scope of claim 1 of the '584 patent as interpreted by HMR." Id. at 2. Andrx further contended that "if HMR were to assert that claim 1 of the '584 patent includes SR2 beads that release not less than 65% of the

total diltiazem after 18 hours under the doctrine of equivalents, that construction [would] require the claims of the '584 patent to include the prior art" and HMR's own expert "Dr. James W. McGinity has confirmed that United States Patent Nos. 5,002,776 and 4,894,240 disclose a delayed release diltiazem bead that releases 65% of the total diltiazem after 18 hours." *Id.* at 3.

On June 9, 1999, the FDA's approval of Andrx's prior approval supplement to its ANDA No. 74-752 became effective. *See* Bennett Decl. at ¶ 23. Also on June 9, 1999, over four months after Andrx filed its Second Supplemental Para. IV Patent Certification, Andrx and HMRI entered into a stipulation settling the HMRI/Andrx patent litigation, and terminated the HMRI/Andrx Agreement.

The stipulation settling the HMRI/Andrx patent infringement action provided that: (1) HMRI continues to assert that the formulation of the Andrx product identified in the complaint did and continues to infringe the '584 patent; and Andrx continues to assert that it does not or that such patent is invalid (Stip. at ¶ 5); (2) on September 11, 1998, Andrx filed a supplement to ANDA 74-752 with the FDA which provided a reformulation of the product that Andrx intends to sell; i.e., a modification in formulation and the dissolution specification for one of the intermediates for the product—diltiazem hydrochloride extended-release SR2 pellets; (3) on February 3, 1999, Andrx certified to HMRI that the reformulated product reflected in the supplement does not infringe HMRI's patents; (4) Andrx intends to market the reformulated product following FDA approval and, unless it obtains a license from HMRI prior to that time, shall not market in the U.S. its earlier version of said product; (4) the reformulated product has SR2 pellets with average dissolution at 18 hours of not less than

68%; (5) HMRI stipulates that it will not prosecute a claim alleging patent infringement as to the reformulated product or seek to enjoin Andrx from marketing the reformulated product provided that the dissolution values are met or exceeded; (6) approval by the FDA of the reformulated product shall constitute final judgment under the September 24, 1997 HMRI/Andrx Agreement; and (7) any obligations arising under Paragraph 7(B) of the September 24, 1997 HMRI/Andrx Agreement (regarding license fees to be paid if Andrx had exercised its option and obtained a license from HMRI) shall be deemed fully satisfied without any further or other payments by either party to the other. *See* HMRI Appendix, Ex. 8, 6/9/99 Stipulation ("Settlement Agreement") in HMRI/Andrx patent case.

On June 23, 1999, Andrx began to commercially market Cartia XT and Andrx's 180-day period of exclusivity began to run. Since the time it has been marketed, Andrx's generic drug, Cartia XT, has been sold at a lower price than HMRI's Cardizem CD.

On June 24, 1999, the court entered an order dismissing the HMRI/Andrx patent infringement action.

By June 1999, when the HMRI/Andrx Agreement was terminated, HMRI had paid Andrx more than $89.83 million under the terms of that Agreement.

C. Consolidated Suits Against Defendants

These cases involve claims that the Defendants violated section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and various state antitrust and unfair competition statutes. Plaintiffs allege the following contract, combination or conspiracy in restraint of trade: Defendant Andrx developed a generic drug which is the bioequivalent to the Hoechst Defendants' prescription drug Cardizem CD. Andrx's generic drug was approved by

the FDA for sale and could have entered the U.S. market on or about July 9, 1998. Andrx, however, did not enter the market at that time because it had agreed with its horizontal competitor, HMRI, that it would delay the entry of its generic version of Cardizem CD in exchange for, *inter alia*, non-refundable payments of $40 million per year from HMRI. Plaintiffs allege that this agreement is embodied in a September 24, 1997 document executed by Defendants HMRI and Andrx (the "HMRI/Andrx Agreement").

The HMRI/Andrx Agreement was executed nine days after the FDA preliminarily approved Defendant Andrx's generic drug as the first AB-rated generic bioequivalent for Cardizem CD. It is alleged that, under the terms of the Agreement, Defendant Andrx agreed not to market its generic drug when it received FDA approval, and agreed not to transfer, assign, or relinquish its right to a 180-day exclusivity period that Andrx would enjoy once it finally did begin to market its generic version of Cardizem CD, and Defendant HMRI agreed to pay Andrx $10 million quarterly, beginning on the date the Andrx product received FDA approval, and for as long as Andrx complied with the terms of the HMRI/Andrx Agreement. Thus, it is alleged that the HMRI/Andrx Agreement not only protected HMRI from competition from Andrx, but it also protected HMRI from competition from other generic competitors because Andrx's delayed entry would postpone the start of its 180-day exclusivity period, and Andrx's agreement not to give up or transfer its right to that 180-day period of exclusivity would preclude other generic competitors from entering the market until that 180-day exclusivity period expired.

D. FTC Complaint Against Defendants

On March 16, 2000, the Federal Trade Commission filed a complaint against HMRI, Carderm Capital L.P., and Andrx Corp. alleging that (1) the HMRI/Andrx Agreement constitutes an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45;[5] (2) HMRI had the specific intent to preserve its monopoly in the relevant market and narrower markets contained therein, and its actions—including proposing, negotiating and entering into the HMRI/Andrx Agreement and its proposal of a similar agreement with Biovail—created a dangerous probability that it would accomplish its monopolistic objectives, in violation of Section 5 of the FTC Act, as amended; (3) Defendants acted with the specific intent that HMRI monopolize the relevant market and engaged in overt acts described in the FTC complaint in furtherance of a conspiracy to monopolize the relevant markets, in violation of Section 5 of the FTC Act, as amended; and (4) the acts and practices described in the FTC complaint are anti-competitive in nature and tendency and constitute unfair methods of competition in violation of Section 5 of the FTC Act, as amended.

A hearing on the FTC complaint is set for November 14, 2000.

II. Summary Judgment Standard

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving

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[5] The Supreme Court has observed that "[t]he FTC Act's prohibition of unfair competition and deceptive acts or practices, 15 U.S.C. § 45(a)(1), overlaps the scope of § 1 of the Sherman Act, 15 U.S.C. § 1, aimed at prohibiting restraint of trade". *California Dental Ass'n v. Federal Trade Comm'n*, 526 U.S. 756, ___ n. 3, 119 S. Ct. 1604, 1609 n. 3 (1999).

party is entitled to judgment as a matter of law. Fed.R. Civ. P. 56(c). The central inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). After adequate time for discovery and upon motion, Rule 56(c) mandates summary judgment against a party who fails to establish the existence of an element essential to that party's case and on which that party bears the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The movant has an initial burden of showing "the absence of a genuine issue of material fact." *Celotex*, 477 U.S. 317, 323. Once the movant meets this burden, the non-movant must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

III. Analysis

The Sherman Act Class Plaintiffs and the Individual Sherman Act Plaintiffs argue that Defendants committed a *per se* violation of Section 1 of the Sherman Act when they entered into the September 24, 1997 HRMI/Andrx Agreement because it embodies an agreement to allocate the U.S. market for Cardizem CD and its bioequivalent AB-rated generics between HMRI and Andrx, who are horizontal competitors, and thus reduced competition, fixed the price of a widely prescribed heart medication, and unreasonably restrained trade. State Law Plaintiffs likewise assert that, because each of the jurisdictions implicated in their state law claims either follow federal Sherman Act precedent or find federal case law persuasive, the HMRI/Andrx Agreement of September 24,

1997 similarly constitutes a *per se* violation of the relevant state antitrust statutes.

The crux of Plaintiffs' argument is that well-established precedent and the undisputed facts show that: (1) agreements between actual or potential horizontal competitors to allocate markets are *per se* violations of the relevant antitrust laws; (2) the HMRI/Andrx Agreement is an agreement between actual or potential horizontal competitors to allocate markets, and thus the HMRI/Andrx Agreement constitutes a *per se* violation of the relevant antitrust laws; and (3) once a particular type of restraint has been placed in a *per se* category; i.e., horizontal market allocation agreement, it is conclusively presumed to be an unreasonable restraint of trade without an elaborate inquiry into purpose, power, or effects. *See, e.g., Topco*, 405 U.S. at 607; *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 221-22 (1940).

Defendants respond that the reasonableness of this alleged restraint of trade cannot be analyzed under the *per se* rule because the Agreement: (1) is not between actual or potential horizontal competitors; (2) does not allocate markets or fix prices and thus does not fall within the category of business practices analyzed under the *per se* rule; (3) is not a "naked" restraint of trade but rather was an agreement that was reasonably ancillary to pro-competitive activity; (4) is analogous to a patent settlement and thus should be analyzed under the rule of reason; and (5) is immunized from antitrust liability under the *Noerr-Pennington* doctrine. Defendant Andrx further responds that Plaintiffs' motions should be denied because determination of the issue presented will not materially simplify or expedite these cases. The Court addresses each of these arguments in turn, beginning with Andrx's argument that partial summary judgment on the issue presented is inappropriate.

A. Propriety of Partial Summary Judgment

Defendant Andrx argues that Plaintiffs' motions for partial summary judgment are improper because resolution of the issue presented will not streamline the litigation process, materially shorten discovery or trial, or conserve judicial resources. This Court disagrees. Plaintiffs clarify that they seek only a ruling that the HMRI/Andrx Agreement is a naked horizontal market allocation agreement and is thus a *per se* violation of the relevant antitrust laws, putting aside for the time being all issues of causation, injury and damages required for private recovery under section 4 of the Clayton Act, 15 U.S.C. § 15. Although Plaintiffs will still be required to prove causation, injury and damages, a decision that the Agreement is *per se* unreasonable will obviate the need for an "elaborate inquiry into the reasonableness of a challenged business practice" and the costs associated with such an inquiry. *See Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332, 343 (1982). Resolution of the issue presented here will greatly narrow the scope of discovery, will streamline the issues to be decided at trial, and will thus serve the interests of judicial economy. Other courts have similarly entertained motions for summary judgment on the issue whether a defendant's challenged activities were illegal *per se* under section 1 of the Sherman Act. *See Arizona v. Maricopa*; *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *New York ex rel. Spitzer v. Saint Francis Hosp.*, 94 F. Supp. 2d 399, 2000 WL 370531 (S.D. N.Y. April 10, 2000).

B. Per Se Analysis of the Challenged Restraint

The Court now considers whether the challenged restraint of trade is susceptible to analysis under the *per se* mode of analysis. The Court begins with a general

description of the essential elements of Plaintiffs' Sherman Act and state law antitrust claims and the *per se* mode of analysis. It then clarifies that the question as to which mode of analysis is to be applied presents a question of law for the Court and that the critical inquiry, regardless of the mode of analysis, is whether the challenged restraint restricts rather than enhances competition.

1. General Principles

a. Violations of Section 1 of the Sherman Act

"The essential elements of a violation of Section 1 of the Sherman Act are: 1) a contract, combination or conspiracy; 2) affecting interstate commerce; 3) which imposes an 'unreasonable' restraint on trade." *White and White, Inc. v. American Hosp. Supply Corp.*, 723 F.2d 495, 504 (6th Cir. 1983). The courts use two methods of analysis, the *per se* rule and the rule of reason, to determine "whether restraints of trade unreasonably restrict competition." *Cooperative Theatres*, 845 F.2d at 1370. "[T]he first employs a presumption that an agreement is an antitrust violation, thus invoking a per se illegality rule to classify the agreement; the second, called 'rule of reason' analysis, requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint of trade." *Betkerur v. Aultman Hosp. Ass'n,* 78 F.3d 1079, 1088 (6th Cir. 1996) (internal quotes and citations omitted).

b. State Law Antitrust Claims

It is not disputed that the state antitrust statutes at issue here either follow federal Sherman Act precedent or find federal case law persuasive. Accordingly, a decision that the HMRI/Andrx Agreement is illegal *per se*

under § 1 of the Sherman Act will likewise result in a similar decision under the relevant California, District of Columbia, Michigan, Minnesota, New York, North Carolina, Tennessee and Wisconsin antitrust statutes.[6]

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[6] *See Marin County Bd. of Realtors, Inc. v. Palsson*, 16 Cal. 3d 920, 925, 130 Cal. Rptr. 1, 549 P.2d 833 (1976), *Truta v. Avis Rent a Car System, Inc.*, 193 Cal. App. 3d 802, 822, 238 Cal. Rptr. 806 (Cal. App. 1987) (observing that California's Cartwright Act "is patterned after the federal Sherman Anti-trust Act and decisions under the latter are applicable as an aid to a decision in interpreting the former"); D.C. Code Ann. § 28-4502 (D.C.'s counterpart to § 1 of the Sherman Act) and § 28-4515 (1998) (expressly stating the intent that the courts are to use federal precedent interpreting federal antitrust laws as a guide to interpretation of D.C.'s antitrust laws); Mich. Comp. Laws § 445.784 (1999) (expressly directing the courts to give "due deference to interpretations given by the federal courts to comparable antitrust statutes, including, without limitation, the doctrine of *per se* violations" in construing the Michigan Antitrust Reform Act); *State by Humphrey v. Alpine Air Prod., Inc.*, 490 N.W.2d 888, 894 (Minn. App. 1992) (observing that the "Minnesota court's have consistently held that Minnesota antitrust law is to be interpreted consistently with the federal courts' construction of federal antitrust law"), *aff'd*, 500 N.W.2d 788 (1993); *People v. Rattenni*, 179 A.D.2d 691, 692, 578 N.Y.S.2d 257 (N.Y. App. Div. 1992) (observing that "[a]lthough we do not move in lockstep with the Federal courts in our interpretation of antitrust law . . . the Donnelly Act . . . should generally be construed in light of Federal precedent" and further observing that "[i]t is well established that the horizontal customer allocation agreement would constitute a *per se* violation of the Sherman Act, the federal antitrust statute, and there is no reason for a different conclusion under the New York Statute"), *aff'd*, 81 N.Y.2d 166, 597 N.Y.S.2d 280, 613 N.E.2d 155 (1993); *DKH Corp. v. Rankin-Patterson Oil Co., Inc.*, 131 N.C. App. 126, 506 S.E.2d 256, 258 (N.C. App. 1998) (observing that the North Carolina courts will look to federal antitrust decisions for guidance in determining the scope and meaning of North Carolina's antitrust statute); *State ex rel. Leech v. Levi Strauss*, 1980 WL 4696 at *2 n. 2 (Tenn. Chancery Ct. 1980) (observing that "[a]uthorities which define the character of private damage suits under the federal anti-trust statutes, particularly the Sherman Act, are most persuasive"); Tenn. Code Ann. §§ 47-25-101 (1999) (providing

c. Per Se Analysis

The Supreme Court has observed that "certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anti-competitive that each is illegal *per se* without inquiry into the harm it has actually caused." *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984). *See also Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332 (1982) (horizontal price-fixing arrangement); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (per curium) (horizontal market allocation agreement); *Topco*, 405 U.S. at 608 (observing that "[o]ne of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"); *Cooperative Theatres*, 845 F.2d 1367 (6th Cir. 1988) (horizontal agreements to allocate markets among competitors); *Blackburn v. Sweeney*, 53 F.3d 825 (7th Cir. 1995) (same). Accordingly, "[i]n those horizontal price-fixing [and market allocation] cases where the per se rule applies, the only inquiry is whether there was an agreement to restrain trade, since the unreasonableness of the restraint is conclusively presumed regardless of whether the rule of reason would lead to a different result." *Re/Max Int'l v. Realty One, Inc.*, 900 F. Supp. 132, 148 n. 8 (N.D. Ohio, 1995) (citing *Maricopa County Medical Soc'y*, 457 U.S.

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that any "arrangements, contracts, [and] agreements . . . which tend to lessen . . . full and free competition" are unlawful); *State v. Waste Management of Wis., Inc.*, 81 Wis. 2d 555, 261 N.W.2d 147, 155 (1978) (observing that conspiracies in restraint of trade under the Sherman Act are likewise conspiracies in restraint of trade under the Wisconsin antitrust act); *Indep. Milk Producers Co-op v. Stoffel*, 102 Wis. 2d 1, 298 N.W.2d 102, 104-05 (Wis. Ct. App. 1980) (observing that "[c]onduct labeled as *per se* illegal includes price fixing, group boycotts, horizontal market allocation, resale price maintenance, and tying arrangements").

at 344), *aff'd*, 173 F.3d 995 (6th Cir. 1999), *petition for cert. filed*, 68 U.S.L.W. 3138 (Aug. 17, 1999) (No. 99-294).

As Professor Hovenkamp explains, "[c]ourts often say that a 'naked' horizontal restraint is illegal 'per se.' What this label means in practice is that (a) neither a relevant market nor an estimate of the defendants' market power must be established to prove that the restraint is unlawful; (b) harmful effects are presumed; and (c) the range of permissible defenses is severely limited." 11 H. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 1910a at 252 (1998 ed.) (footnotes omitted). "[T]he justification for the per se rule rests on an implicit and rather loose 'cost-benefit' analysis concluding that for certain classes of restraints the added costs of applying a rule of reason are not justified by the resulting improvement in accuracy of outcome." *Id.* The rule "is based on the premise that particular restraints are unreasonable as a class. As a result, once the tribunal concludes that the restraint at issue is within the class, further inquiry into the merits of that particular restraint is unwarranted." *Id.* at ¶ 1910b, p. 252 (emphasis in original).

The Sixth Circuit has similarly observed, "a court's choice between a per se rule and 'rule of reason' analysis is driven largely by analogy. A court should find a per se antitrust violation only when prior cases have established the anti-competitive effects of a sufficiently similar business practice," *Betkerur*, 78 F.3d at 1089. Business practices condemned under the *per se* rule include horizontal agreements to allocate markets and to fix prices. *See Copperweld Corp.*, 467 U.S. at 768. The Sixth Circuit has further observed that, " 'horizontal' restraints—that is, agreements among competitors at the same level of the market structure—are particularly sus-

pect because they typically serve no purpose other than to stifle competition," *Betkerur*, 78 F.3d at 1092.

d. Question of Law for the Court

The question presented here; i.e., whether to apply a *per se* or rule of reason mode of analysis in determining the reasonableness of the challenged restraint of trade, is a question of law for the Court. *See In re American Honda Motor Co., Inc. Dealership Relations Litig.*, 941 F. Supp. 528, 562 (D. Md. 1996). "While applying any one of antitrust's modes of analysis might involve many fact questions, the selection of a mode is entirely a question of law," 11 H. Hovenkamp, *supra*, ¶ 1909b at 251 (citing *Maricopa County Medical Society*, 457 U.S. at 337 n. 3). As Professor Hovenkamp observes, "the entire premise of the per se rule is that *judicial* experience with a certain class of restraints justifies more expedited treatment." Hovenkamp, *supra* ¶ 1909b at 251 (citing *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 100-101 (1984)). Accordingly, the testimony of Defendant HMRI's expert, Dr. Roger Blair, opining that the HMRI/Andrx Agreement should be analyzed under the rule of reason rather than the *per se* rule, inappropriately renders an opinion on a question of law that rests solely within the province of the Court and thus is not considered here.

e. Critical Inquiry—Does the Challenged Restraint Enhance Competition

Despite the identification of different modes of analysis for determining the reasonableness of a challenged restraint of trade, the Supreme Court has observed that the ultimate goal is to answer the critical question whether the challenged restraint enhances or impairs

competition. Regardless of whether the "unreasonableness" finding " 'is the product of a presumption [under a *per se* analysis] or actual market analysis [under a rule of reason analysis], the essential inquiry remains the same—whether or not the challenged restraint enhances competition.' " *California Dental Ass'n v. Federal Trade Comm'n*, 526 U.S. 756, ___, 119 S. Ct. 1604, 1617 (1999) (quoting *Nat'l Collegiate*, 468 U.S. at 104). Thus, "[e]very antitrust suit should begin by identifying the ways in which a challenged restraint might possibly impair competition," 7 P. Areeda, *Antitrust Law* ¶ 1503a at 372 (1986 ed.). This applies to *per se* cases as well. "Although a per se rule is seemingly satisfied merely by showing, say, 'price fixing,' specifying the competitive evil helps reassure us that the challenged conduct actually falls in that category." Id. at 372, n. 1. "Identifying the type of possible harm to competition is the first essential step." 7 P. Areeda, *supra*, ¶ 1503 at 374.

Accordingly, this Court will first construe the terms of HMRI/Andrx Agreement and identify whether the challenged restraints in that Agreement might, on their face, impair or enhance competition. The Court will then address Defendants' arguments that the HMRI/Andrx Agreement is: (1) not between actual or potential horizontal competitors; (2) not a market allocation or price fixing agreement; (3) not a "naked" restraint of trade but rather is an agreement reasonably ancillary to a pro-competitive activity; (4) analogous to a patent settlement agreement and thus should be analyzed under the rule of reason mode of analysis; and (5) immunized from antitrust liability under the *Noerr-Pennington* doctrine.

2. Construction of the HMRI/Andrx Agreement —Identifying Whether the Challenged Restraints Enhance or Inhibit Competition

a. General Principles

The HMRI/Andrx Agreement is to be interpreted in accordance with the general principles of contract law, and, as provided in ¶ 11 of that Agreement, "all the terms and provisions" "shall be construed under the laws of the State of Florida." Under Florida law, "the interpretation of a written contract is a matter of law to be determined by the court." *DEC Elec., Inc. v. Raphael Constr. Corp.*, 558 So. 2d 427, 428 (Fla. S. Ct. 1990). Accordingly, this Court does not consider the testimony of Defendant HMRI's experts, A. Bennett and R. Blair, or that of Defendant Andrx's Vice President/General Counsel, Scott Lodin, that construe the terms of the HMRI/Andrx Agreement or proffer testimony that is contrary to this Court's construction of the Agreement. *See* A. Bennett Decl. at ¶¶ 11, 12; R. Blair Decl. at ¶¶ 5, 8, 17; and S. Lodin Decl. at ¶¶ 8, 15, 17-20, 22-23, 25.

"Contract interpretation principles under Florida law require [the Court] to look first at the words used on the face of the contract to determine whether that contract is ambiguous. It is well settled that the actual language used in the contract is the best evidence of the intent of the parties and, thus, the plain meaning of that language controls." *Rose v. M/V "Gulf Stream Falcon"*, 186 F.3d 1345, 1350 (11th Cir. 1999) (citations omitted). Furthermore, "under Florida law, . . . 'whereas' or other prefatory clauses are not binding" and "although, the 'whereas' clause may be evidence of parties' intent, [the Court] need not even look to the 'whereas' clause if the operative portion of the contract is unambiguous." *Id.* at 1350.

b. The HMRI/Andrx Agreement

To give the Court's construction of the HMRI/Andrx Agreement some context, the Court sets forth the following undisputed facts. On September 15, 1997, the FDA issued tentative approval of Andrx's ANDA, which was an indication that the ANDA would be approved as soon as it was legally eligible; i.e., on or about July 8, 1998, the date the 30-month Hatch-Waxman waiting period was due to expire. Less than ten days after the FDA's tentative approval, the Defendants entered into the HMRI/Andrx Agreement. The Agreement was entered into while the patent infringement action between HMRI and Andrx was pending. The Agreement, however, was not presented to, filed in, or approved by the court presiding over that patent infringement action.

On September 11, 1998, Andrx filed a prior approval supplement to its ANDA No. 74-752 seeking permission to add a small amount of a new ingredient to the SR2 bead coating and to change the dissolution specification for the SR2 bead from not less than 55% of total diltiazem being released after 18 hours to not less than 65% being released after 18 hours. On June 9, 1999, the FDA's approval of Andrx's prior approval supplement to its ANDA No. 74-752 became effective. Also on June 9, 1999, HMRI and Andrx filed a stipulation agreeing to settle the HMRI/Andrx patent case. Andrx did not commence marketing or selling its generic version of Cardizem CD until June 23, 1999, after the HMRI/Andrx Agreement was terminated and the HMRI/Andrx patent case was settled.

The Court now construes the terms of the HMRI/Andrx Agreement. The Agreement acknowledged that Andrx had formulated a bioequivalent or generic version of Cardizem CD and had filed an ANDA with the FDA seeking the right to sell the generic drug identified in its

ANDA. The Agreement identified Andrx's generic version of Cardizem CD as "the Andrx Product" and defined it as "the product Andrx intends to sell pursuant to the ANDA on file with the FDA *and as said ANDA may be amended consistent with this subparagraph.*" Agreement at ¶ 8(B)(iv) (emphasis added). Thus, the Andrx Product which was the subject of the HMRI/Andrx Agreement was that described in Andrx's ANDA No. 74-752 and that described in any amendment or modification to Andrx's ANDA No. 74-752 not requiring withdrawal of that ANDA or submission of a new ANDA. *Id.*

The Agreement also acknowledged that: (1) the Andrx Product was the subject of a pending patent infringement action brought by HMRI against Andrx; (2) HMRI had asserted its intent to seek an injunction barring Andrx from marketing, distributing or selling the Andrx Product prior to entry of a final and unappealable order or judgment in the HMRI/Andrx patent infringement case; (3) Andrx was aware of the financial risks it faced if HMRI sought and obtained injunctive relief or ultimately prevailed in its patent infringement action, as well as the risk of losing substantial revenues from the Andrx Product if it were to refrain from selling the Andrx Product until after a final and unappealable order or judgment was issued in its favor in the HMRI/Andrx patent case; and (4) although HMRI and Andrx intended to fully and vigorously litigate the infringement and validity issues in the pending HMRI/Andrx patent case, they also wished to reduce the risk of loss inherent in that litigation. *See* HMRI/Andrx Agreement at 1-2 ("Whereas" clauses).

Under the unambiguous terms of the HMRI/Andrx Agreement, Andrx agreed that it would not "commence the commercial sale" of its generic version of Cardizem

CD (which was the subject of its pending ANDA) "*or other bioequivalent or generic version of Cardizem CD*" in the United States either directly or indirectly until the earlier of: (1) entry of a final and unappealable order or judgment in the pending HMRI/Andrx patent infringement case; (2) Andrx obtained a license from HMRI after exercising its option under the terms of the HMRI/Andrx Agreement;[7] or (3) HMRI provided notice of the date that either HMRI or a third party licensee was authorized to make its first commercial sale of a bioequivalent or generic version of Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A) (emphasis added).

Andrx further agreed that, while the HMRI/Andrx patent infringement case was pending, it would "diligently prosecute" its ANDA and would "not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto." *Id.* Andrx was allowed to modify or amend its ANDA as long as that did not require it to withdraw its existing ANDA. ¶ 8(B)(iv). The clear intent here was to protect the 180-day period of exclusivity awarded to Andrx under the Hatch-Waxman Amendments as the first-filed ANDA with a Paragraph IV certification.

Andrx also agreed to dismiss, without prejudice, its antitrust and unfair competition counterclaims filed against HMRI in the HMRI/Andrx patent case. As between HMRI and Andrx, the dismissal was deemed to be with prejudice on the effective date of a final and unappealable order or judgment in the HMRI/Andrx

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[7] The Agreement provided three opportunities for Andrx to exercise its option to obtain a license, including an opportunity to exercise its option and obtain a license while the HMRI/Andrx suit remained pending; i.e., in January 2000 (18 months after FDA approval of the Andrx Product). *See* HMRI/Andrx Agreement ¶ 6(A)(ii).

patent case "provided that HMRI had fully complied with the terms" of the Agreement. *See* HMRI/Andrx Agreement at ¶ 2(C).

Accordingly, on its face, the HMRI/Andrx Agreement: (1) restrained Andrx from marketing its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained; (2) restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to Andrx's ANDA No. 74-752; and (3) restrained Andrx from relinquishing or otherwise compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments.

HMRI agreed, under the unambiguous terms of the HMRI/Andrx Agreement, that it would not seek preliminary injunctive relief against Andrx, that it would provide Andrx with copies of changes it proposed to the FDA regarding its Cardizem CD package insert and immediate container label, and that it would notify Andrx of any labeling change approved by the FDA regarding Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A), 2(B).

HMRI also agreed that it would make interim payments to Andrx in the amount of $40 million per year, payable quarterly, and beginning on the date Andrx's generic version of Cardizem CD received FDA approval (July 8, 1998). *Id.* at ¶ (4)(A). These interim payments were to end on: (1) the date of a final and unappealable order or judgment in the HMRI/Andrx patent case;[8]

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[8] The HMRI/Andrx Agreement provided that, in the event there was a final unappealable determination in the HMRI/Andrx patent case that did not determine the validity, enforceability or infringement of the '584 patent and HMRI notified Andrx in writing

(2) in the event HMRI notified Andrx that it intended to license its intellectual property for the purpose of selling a generic version of Cardizem CD to a third party or intended to use this property itself for the same purpose, then the interim payments were to end on the earlier of: a) the expiration date of the required notice period, or b) the date Andrx effected its first commercial sale of the Andrx Product; or (3) in the event Andrx exercised its option to acquire a license from HMRI, then interim payments were to end on the date the license agreement became effective. *See* HMRI/Andrx Agreement at ¶¶ 4(A)-(C).

The Agreement, despite calling the interim quarterly payments "nonrefundable," required repayment if, prior to the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case: (1) Andrx commenced the commercial sale of the Andrx Product in the United States, directly or indirectly (¶ 8(B)(i)); (2) Andrx commenced the commercial sale of other bioequivalent or generic versions of Cardizem CD in the United States, directly or indirectly (¶ 8(B)(i)); (3) Andrx failed to diligently prosecute or withdrew its ANDA for the Andrx Product or relinquished or otherwise compromised any right accruing under its ANDA (¶ 8(B)(i)); (4) Andrx transferred, sold, or assigned, without HMRI's express written consent, any option or

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within 30 days that it continued to believe that the Andrx Product infringed the '584 patent and that it would refile its action and did so within the time frame set forth in ¶ 8(C), then this renewed action would continue the obligations and rights set forth in the Agreement as if no final, unappealable determination had been entered. *See* HMRI/Andrx Agreement at ¶ 8(C). Accordingly, these interim payments and Andrx's agreement not to begin commercial marketing of the Andrx Product or to compromise its right to the 180-day period of exclusivity could continue beyond the time a final and unappealable judgment or order took effect in the HMRI/Andrx patent case.

licensing rights issued pursuant to the HMRI/Andrx Agreement (¶ 8(B)(i)); or (5) Andrx stipulated in writing or in open court and on the record that the '584 patent was valid and that the Andrx Product infringed the '584 patent before there was a court determination on those issues (¶ 8(D)). Each of these events, also terminated the Agreement. *See* HMRI/Andrx Agreement at ¶¶ 8(B)(i), 8(D).

HMRI also agreed to pay Andrx $100 million per year,[9] less the amount of interim payments previously paid to Andrx under the terms of the Agreement, if: (1) Andrx obtained a final and unappealable order or judgment in the HMRI/Andrx patent case determining that the '584 patent was invalid or unenforceable or that the Andrx Product did not infringe the '584 patent, (¶ 3(B)); (2) HMRI dismissed the HMRI/Andrx patent infringement case prior to the effective date of a final and unappealable order in the HMRI/Andrx patent case (¶ 8(A)); or (3) there was a final and unappealable determination in the HMRI/Andrx patent case that did not determine the issues of the '584 patent's validity, enforcement or infringement and HMRI failed to notify Andrx, within 30 days of that determination, that it continued to believe that the Andrx Product infringed the '584 patent and that it would refile, and did refile, its patent infringement action (¶ 8(C)).

HMRI further agreed to grant Andrx an irrevocable option to acquire a non-exclusive license to all intellectual property HMRI owned or controlled that Andrx may need to market its generic version of Cardizem CD in the United States. *See* HMRI/Andrx Agreement at ¶ 5.

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[9] HMRI and Andrx stipulated that, for the purposes of this Agreement, "the profits that Andrx would have realized from the sale of the Andrx Product would be $100 million per year after FDA approval." HMRI/Andrx Agreement at ¶ 3(A).

Andrx was prohibited from transferring, selling, or assigning, without HMRI's express written consent, its option to acquire a license from HMRI or any rights granted to Andrx if it did exercise that option and acquired a license. *Id.* at ¶ 8(B). Andrx had only three opportunities to exercise the option to acquire a license: (1) within 30 days from the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(i)); (2) in the event a final and unappealable order or judgment had not been entered, then beginning at the earlier of: a) 18 months after FDA approval (January 2000), or b) the effective date of FDA approval for a third party to make and market a bioequivalent or generic version of Cardizem CD (which, under the terms of the Hatch-Waxman Amendments, could not occur until 180 days after Andrx either began commercial marketing of its generic version of Cardizem CD or there was a court decision that the '584 patent was invalid or not infringed by Andrx's generic drug), and ending 30 days after the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(ii)); or (3) in the event that HMRI notified Andrx that HMRI or another third party would be using HMRI's intellectual property for the purpose of selling a generic version of Cardizem CD, Andrx could exercise its option at any time beginning on the date it received notice from HMRI and ending on the effective date of a final and unappealable order or judgment in the HMRI/Andrx patent case (¶ 6(A)(iii)).

In the event Andrx decided to exercise its option to acquire a license, the Agreement also provided for license fees and royalty payments. *See* HMRI/Andrx Agreement at ¶ 7. HMRI was required to refund the license fees and royalty payments if: (1) a final and unappealable order or judgment in the HMRI/Andrx

patent case determined that the '584 patent was invalid or unenforceable or was not infringed (¶ 7(B)(i)); or (2) HMRI dismissed the HMRI/Andrx patent infringement action prior to the effective date of a final and unappealable order or judgment (¶ 8(A)).

Both parties agreed that: (1) they would not ask the court presiding over the HMRI/Andrx patent case for an order increasing or decreasing the Hatch-Waxman 30-month waiting period (¶ 2(D)); (2) "except as otherwise required by law or as otherwise may be requested by the court" in the HMRI/Andrx patent case, the terms and existence of the Agreement would be kept confidential (¶ 9); and (3) the Agreement "and any drafts thereof or any documents or records pertaining thereto or information derived therefrom" would not be introduced into evidence in the HMRI/Andrx patent case "or any other litigation for any purpose." HMRI/Andrx Agreement at ¶ 9.

c. Restraints of Trade and Likely Effects on Competition

On its face, the Agreement: (1) restrained Andrx from marketing its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained; (2) restrained Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to its ANDA No. 74-752, and thus restrained Andrx from marketing non-infringing or potentially non-infringing versions of Cardizem CD; and (3) restrained Andrx from relinquishing or otherwise compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments. The HMRI/Andrx Agree-

ment thus inhibited rather than enhanced generic competition for Cardizem CD and allocated the entire United States market for Cardizem CD and its bioequivalents to HMRI during the life of that Agreement. By restricting generic competition, the Agreement also allowed HMRI to maintain or fix the price of Cardizem CD at non-competitive price levels.

The Agreement's terms as to the $10 million quarterly payments to Andrx, beginning in July 1998 when Andrx obtained FDA approval of its generic version of Cardizem CD, further restrained generic competition. First, they provided Andrx with an incentive to stay off the market beyond the time when it could have commenced marketing its generic drug (July 1998). They further restrained generic competition by providing Andrx with an incentive not to relinquish its right to the 180-day exclusivity period for marketing that it had obtained under the Hatch-Waxman Amendments from its status as the first generic manufacturer to file an ANDA with a Paragraph IV certification. Other generic drug manufacturers filing second and subsequent ANDAs for generic versions of Cardizem CD were required to wait until Andrx's 180-day exclusivity period expired before they could obtain FDA approval and enter the market. *See Mylan Pharm*, 81 F. Supp. 2d at 33.

This Court concludes that the September 24, 1997 HMRI/Andrx Agreement is unlawful on its face and is a *per se* violation of Section 1 of the Sherman Act. Contrary to Defendants' arguments, the HMRI/Andrx Agreement is an agreement between horizontal competitors to minimize generic competition and to allocate the entire United States market for Cardizem CD to HMRI during the life of the Agreement. *See Topco*, 405 U.S. at 608 (observing that "[o]ne of the classic examples of a per se violation of § 1 is an agreement between competitors at

the same level of the market structure to allocate territories in order to minimize competition"). *See also Palmer*, 111 S. Ct. at 403 (observing that previous competition in the market is not required, that the "defendants in *Topco* had never competed in the same market, but had simply agreed to allocate markets", and further observing that horizontal market allocation agreements "are anti-competitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other"); *Cooperative Theatres*, 845 F.2d at 1372 (observing that "a horizontal agreement to allocate customers between competing companies is a per se violation of Section 1 of the Sherman Act"); *Blackburn v. Sweeney*, 53 F.3d at 827 (observing that "[h]orizontal agreements to allocate markets among competitors are *per se* violations of the Sherman Act"). The Court is not persuaded by Defendants' argument that the HMRI/Andrx Agreement is an agreement that was reasonably ancillary to pro-competitive activity rather than a "naked" restraint of trade.

d. Defendants' Arguments Against Per Se Treatment

1. The HMRI/Andrx Agreement is a Horizontal Agreement

Defendants do not dispute that they perform at the same level of the market structure or that they are currently competitors in the U.S. market for Cardizem CD or its bioequivalents. Nonetheless, Defendants argue here, as they did in their motions to dismiss, that they cannot be considered horizontal competitors because they were neither competitors nor potential competitors during the life of their Agreement. Specifically, Defen-

dants argue that, during that time, they were never in direct competition and, furthermore, cannot be considered potential competitors because, until HMRI's patent claims were resolved, Andrx had no right to compete.[10] Defendants' arguments are without merit. First, it is not necessary that Defendants be actual competitors at the time of their Agreement. *See Palmer*, 111 S. Ct. at 403 (observing that, to prove a *per se* violation, a plaintiff need not show that the defendants had previously competed in the relevant market). Furthermore, Defendants' potential competitor arguments are built on the erroneous presumptions that Andrx's generic drug would infringe the '584 patent and that potential rivalry means the ability to compete free from the risk of patent liability.[11] *See Order* No. 12, Mem. Op. & Order at 117-122.

"An arrangement is said to be 'horizontal' when (1) its participants are *either* (a) actual rivals at the time the agreement is made or (b) potential rivals at the time the agreement is made; *and* (2) the agreement eliminates some avenue of rivalry among participants." 11 H. Hovenkamp, *supra*, ¶ 1901b at 185. Despite arguments to the contrary, HMRI and Andrx were potential rivals at the time the HMRI/Andrx Agreement was made, and the

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[10] In support of this position, Defendant HMRI proffers the testimony of its expert, G. Methvin, opining that it was more likely than not that HMRI would have prevailed on its patent infringement claims, that the Court would have adopted the claim construction urged by Defendant HMRI, and that HMRI would have been entitled to a preliminary injunction in the HMRI/Andrx patent infringement case. The Court does not consider this testimony because it inappropriately renders an opinion on questions of law that rest solely within the province of the Court; i.e., claim construction and the grant or denial of injunctive relief.

[11] Defendants refer to this as competing "without the threat of economic ruin." *See* Andrx Br. at 27.

Agreement eliminated an avenue of rivalry; i.e., Andrx's entry in the market with a generic version of Cardizem CD. Testimony by Andrx's Vice President/General Counsel, Scott Lodin, that, at the time the Agreement was made, Andrx did not consider itself to be a competitor or potential competitor of HMRI is to no avail. *See* S. Lodin Aff'd at ¶ 15. Mr. Lodin's testimony is contrary to this Court's construction of the HMRI/Andrx Agreement; i.e., the plain language of that Agreement reflects that Andrx was considered a potential rival of HMRI in the U.S. market for Cardizem CD and its bioequivalents.[12]

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[12] Mr. Lodin's testimony is also belied by: (1) his earlier testimony that Andrx's "primary goal was to begin selling our product as soon as we could prudently do so, in order to provide consumers with a genuine alternative to HMR's brand name drug and to demonstrate that Andrx was a serious participant in the generic pharmaceutical industry", *Id.* at ¶ 5; and (2) contemporaneous public statements in 1997 and 1998 by both HMRI and Andrx showing that they had no trouble recognizing that they were one another's competitors in the relevant market. *See* Jt. App., Tab 2 at 37, October 1997 Andrx Amendment No. 1 to S-1 filing (where, in SEC filings, Andrx represented to its shareholders that it had submitted ANDAs to the FDA covering, *inter alia*, bioequivalent versions of "Cardizem CD which is marketed by HMR . . . . In September 1997 [Andrx] received tentative FDA approval of its ANDA for the bioequivalent version of Cardizem/registered trademark/ CD. As a result of the HMR Litigation, the FDA may not grant final approval of Andrx's ANDA for Cardizem/registered trademark/CD until after either the HMR Litigation is resolved in Andrx's favor or July 3, 1998 (30 months after HMRI received Andrx's certification that its product does not infringe the patents listed for Cardizem/registered trademark/CD"). *See also* Jt. App., Tab 5 at 9, 1998 Hoechst AG 20-F filing (where HMRI also specifically warned its shareholders that generic competition for its products in general would "erode market share and sales revenues" and, in particular, generic sales of Cardizem CD "would have a material adverse effect on the operating profit of the Group" and further observed that "[a]lthough Cardizem

2. The HMRI/Andrx Agreement Allocates the U.S. Market for Cardizem CD

Andrx sought to compete with HMRI in the sale of Cardizem CD and its bioequivalents. This is evident from its ANDA No. 74-752, its Paragraph IV certification, and the subsequent HMRI/Andrx patent litigation. Within ten days of the FDA's tentative approval of Andrx's generic version of Cardizem CD, Defendants entered into the HMRI/Andrx Agreement. The unambiguous terms of the HMRI/Andrx Agreement allocate the entire U.S. market for Cardizem CD and its bioequivalents to HMRI while compensating Andrx, its potential competitor, $10 million dollars a quarter for not marketing its generic version of Cardizem CD and for not relinquishing or compromising its right to the 180-day period of marketing exclusivity it obtained under the Hatch-Waxman Amendments. This Agreement is a straight forward horizontal market allocation agreement and thus fits within the category of business practices which have long been held illegal *per se* under section 1 of the Sherman Act. *See Topco*; *Palmer*; *Cooperative Theatres*, 845 F.2d at 1372; *Blackburn v. Sweeney*, 53 F.3d at 827.

Defendants' causation arguments do not require a contrary conclusion. Whether Andrx's prior unilateral deci-

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CD . . . is protected by formulation patents that prevent competition by others using the same formulation, a number of companies have filed for approval by the United States Food and Drug Administration ("FDA") of generically substitutable once-daily diltiazem formulations (at least one of which has been approved for marketing), which they assert do not infringe these patents. Should any of these products be marketed and not infringe HMR's patents, it likely would have a material adverse effect on Cardizem CD sales and could have a material adverse effect on the operating profit of the Group. Marketing of such a product could occur as early as 1999").

sion, as opposed to the HMRI/Andrx Agreement, caused it to stay off the market after it had obtained FDA approval and the 30-month Hatch-Waxman waiting period had expired is not at issue here.[13] The anti-competitive effects of HMRI's patent are likewise not at issue. Rather than Andrx's unilateral decisions, the conduct at issue here is Andrx's bilateral agreement with HMRI, its horizontal competitor, that unambiguously allocates the entire market for Cardizem CD and its bioequivalents to HMRI for as long as the Agreement remained in effect. As the Supreme Court observed in *Socony-Vacuum Oil*, 310 U.S. at 224, n. 9, it is well settled that "conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring, (citation omitted). It is the 'contract, combination . . . or conspiracy, in restraint of trade or commerce' which § 1 of the Act strikes down, whether the concerted activity be wholly nascent or abortive on the one hand, or successful on the other."

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[13] *See* S. Lodin Decl. at ¶¶ 8, 14-16, 19, 22 (where Andrx's Vice President/General Counsel testifies that, prior to the time Andrx entered into the HMRI/Andrx Agreement, Andrx had already decided that it would not enter the market until the HMRI/Andrx patent suit was resolved and had already decided that it would not abandon its pending ANDA). The Supreme Court, apparently ignoring a similar defense, held a horizontal market allocation agreement *per se* illegal under § 1 of the Sherman Act. In *Palmer*, the defendant who agreed to withdraw from the Georgia market submitted an affidavit in the district court similarly averring that it had unilaterally decided to withdraw from the Georgia market before it entered into the challenged agreement. *See Palmer v. BRG of Georgia, Inc.*, 874 F.2d 1417, 1418 (11th Cir. 1989), *rev'd*, 498 U.S. 46, 112 L. Ed. 2d 349, 111 S. Ct. 401 (1990). Without regard to the defendant's affidavit as to its unilateral decision, the Supreme Court examined the challenged agreement on its face and held that the horizontal market allocation agreement in *Palmer* was illegal *per se*. *See Palmer*, 111 S. Ct. at 403.

As Professor Hovenkamp has observed, "[h]orizontal agreements are antitrust's most 'suspect' classification" and "*as a class* deserve stricter scrutiny than" unilateral acts or vertical agreements because "they pose the most significant dangers of competitive harm." 11 H. Hovenkamp, *supra*, ¶ 1902a at 190-91 (emphasis in original). "The main threat of horizontal agreements is that they can enable participants to reduce the output of goods in some market, thus causing higher prices, inefficient substitutions, and the resultant losses to consumer welfare," *Id.* at 191. Unilateral acts, on the other hand, "always pose a lower threat than horizontal combinations. By definition, a unilateral act does not limit the activities of actual or potential rivals." *Id.*, ¶ 1902b at 193.

The decisions Defendants rely upon do not support a contrary result. In *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 648-49 (9th Cir. 1981), Westinghouse had entered into technical assistance agreements with some companies granting them licenses to manufacture, use, and sell certain electrical products under Westinghouse's foreign patents. No licenses were granted under Westinghouse's U.S. or Canadian patents. Nothing in the agreements, however, forbid the licensees from manufacturing, using, or selling the products covered by the foreign licenses in the United States or Canada. *Id.* at 645.

At the bench trial, the Government argued, *inter alia*, that they had established the necessary causal link for their antitrust case against Westinghouse by presenting evidence showing that the licensees had sought Westinghouse's approval before they attempted to sell the products listed in the technical assistance agreements in the United States. The district court disagreed, finding that the Government had not met its burden of proof *on the issue of causation* because the licensees had argued

that "they did not act on the basis of an illegal agreement with Westinghouse but rather out of fear of infringing Westinghouse's patents." *Id.* at 648-49 (internal quotes and citations omitted). The Ninth Circuit affirmed the district court's dismissal based on the Government's failure to meet its burden on the issue of causation observing that:

> If fear of patent infringement was the reason [the licensee] sought Westinghouse approval before selling products covered by the Agreements in the United States, then it cannot be said that the resulting lack of competition was the "effect" of the Agreements rather than the effect of Westinghouse's patent. *The government bears the burden of showing causation. It must show that some combination or conspiracy between the parties "actually causes injury to competition," . . . in violation of the antitrust laws. The district court's conclusion that the government failed to show this causal link is amply supported by the record.* . . . The desire of [the licensee] to avoid infringing upon Westinghouse's many patents perhaps even as to products only arguably covered by Westinghouse's patents undoubtedly has an effect on competition, but this is an effect *which results from* the monopoly granted by the patent laws and does not establish an antitrust violation by the companies in this case.

Id. at 649 (citations omitted) (emphasis added).

As clarified in the quoted passage, the critical issue in *Westinghouse* was whether the Government had satisfied its burden of proof by showing the necessary causal link between the alleged antitrust violation and injury. That is not the issue presented here. Rather, Plaintiffs' motions require this Court to: (1) consider the

HMRI/Andrx Agreement and its likely anti-competitive effects; (2) determine whether the challenged Agreement is properly classified as a horizontal market allocation agreement that is susceptible to analysis under the *per se* rule; and if so, (3) apply the *per se* rule and conclude that the restraint of trade created by the Agreement is presumptively unreasonable and thus illegal *per se*.

Defendant HMRI's reliance on *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606, 608 (6th Cir. 1987) is likewise misplaced. In *Miller Insituform*, the issue presented was whether an exclusive licensee violated section 2 of the Sherman Act when it terminated an agreement to sublicense a patent. The Sixth Circuit held there was no violation, reasoning that the exclusive licensee had a lawfully acquired patent and was merely exercising its right, granted under the license, to exclude others from using the patented process that was the subject of its exclusive license. Unlike the situation in *Miller Insituform*, there is no termination of a sublicensing agreement at issue here. Plaintiffs do not base their antitrust claims on HMRI's litigation efforts to maintain its monopoly power under the '584 patent. Rather, their antitrust claims challenge as anti-competitive HMRI's and Andrx's Agreement to have Andrx refrain from entering the market with its generic version of Cardizem CD beyond the time when it could have entered the market, to have Andrx refrain from relinquishing or compromising its pending ANDA (which had the practical effect of delaying entry of other generic versions of Cardizem CD into the market), and to have HMRI pay Andrx tens of millions of dollars as long as it complied with these restraints.

The decision in *Dunlop Co., Ltd. v. Kelsey-Hayes Co.*, 484 F.2d 407, 417-18 (6th Cir. 1973), also fails to advance HMRI's arguments. In *Dunlop Co.*, the court

similarly held that a patent holder, who had the power under its patent to preclude others from marketing its patented product without offending the antitrust laws, could also issue licenses as to its patented products that contained territorial restrictions without violating the antitrust laws. Unlike *Dunlop Co.*, there is no restricted license at issue here that allocates the territorial market for Cardizem C.D. Rather, there is an Agreement between HMRI and Andrx that allocated the entire U.S. market for Cardizem CD and its bioequivalents to HMRI for the life of that Agreement. As discussed more fully *infra*, the Agreement broadly restrains Andrx from marketing not only the allegedly infringing Andrx Product but also other bioequivalent or generic versions of Cardizem CD.

3. The HMRI/Andrx Agreement is Not An Agreement Reasonably Ancillary to Pro-Competitive Activity

As further support for their argument that *per se* analysis is inappropriate here, Defendant HMRI argues that the challenged restraints of trade embodied in the HMRI/Andrx Agreement are reasonably ancillary to the Agreement's central pro-competitive purposes and thus must be analyzed under the rule of reason. Andrx, on the other hand, argues that the Agreement "had no anti-competitive effects at all and in fact had demonstrable pro-competitive effects." Andrx Resp. Br. at 26. The Court disagrees with Defendants and is not persuaded that the broad restraints in the HMRI/Andrx Agreement are ancillary to the allegedly pro-competitive provisions Defendants rely upon to advance their position. The plain terms of the Agreement belie Defendants' argument that this Agreement is the product of a cooperative venture designed to enhance competition and facilitate

product output in the relevant market. *See Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185 (7th Cir. 1985).

Defendants identify the following competition-enhancing qualities of the HMRI/Andrx Agreement: (1) it maintained the status quo, allowed HMRI and Andrx to manage their litigation risks, operated like a court-ordered preliminary injunction with a Fed. R. Civ. P. Rule 65(c) bond and thus facilitated and fostered the expeditious resolution of their patent infringement dispute; (2) it protected HMRI's patent rights and provided Andrx with capital to invent around the '584 patent and thus allowed Andrx an opportunity to enter in the market sooner without the risk of patent liability; and (3) it provided Andrx with an opportunity to obtain a license from HMRI that, if exercised, would allow Andrx to enter the market and compete with HMRI without the risk of patent liability both while the suit was pending (in January 2000, 18 months after Andrx's ANDA obtained FDA approval) and in the event Andrx lost the HMRI/Andrx patent suit. The Court addresses each of these in turn.

First, Defendants' claims that the HMRI/Andrx Agreement merely "settled" HMRI's claim for injunctive relief and maintained the status quo lack merit. The HMRI/Andrx Agreement did not maintain the status quo. HMRI's interim payments to Andrx in the amount of $10 million per quarter negate this claim. More importantly, the restraints imposed by the Agreement exceed those generally available under a court-ordered preliminary injunction: (1) it barred Andrx's entry into the market beyond resolution of the HMRI/Andrx patent suit in the district court; (2) it provided large interim payments to Andrx that created an incentive for Andrx to stay off the market with its generic drug after obtaining FDA

approval in contrast to a Rule 65(c) bond, issued at the Court's discretion, to cover damages actually incurred if HMRI was successful in obtaining a preliminary injunction but ultimately unsuccessful in its infringement action; (3) it barred Andrx from relinquishing or compromising its right to the 180-day period of exclusivity it obtained under the Hatch-Waxman Amendments and, in contrast to a court-ordered Rule 65(c) bond, provided large interim payments to Andrx that created an incentive for Andrx not to withdraw, relinquish or otherwise compromise its right to the 180-day period of marketing exclusivity; and (4) it barred Andrx from marketing other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending HMRI/Andrx patent case, including the reformulated generic drug described in Andrx's September 11, 1998 prior approval supplement to its ANDA No. 74-752.[14]

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[14] HMRI had available the entire 30-month waiting period under Hatch-Waxman in which to seek an injunction. Andrx could not enter the market until that two and one-half year period expired, but HMRI did not seek any such relief in the HMRI/Andrx patent action. Had HMRI sought and obtained injunctive relief, it would have obtained *Noerr-Pennington* immunity, protected its patent, and could have sought a Rule 65(c) bond that, most likely, would not require it to pay interim quarterly payments to Andrx in the amount of $10 million. HMRI, however, did not seek an injunction.

Unlike a court-ordered preliminary injunction, this Agreement was never presented to, filed in, or approved by the court presiding over the HMRI/Andrx patent case. The restraints embodied in the HMRI/Andrx Agreement are the result of a purely private agreement and, as this Court has previously determined, are not immune from antitrust liability under the *Noerr-Pennington* doctrine. *See* Order No. 12, Mem. Op. & Order Denying Defendants' Motions to Dismiss at 25-45. Here, there was no judicial finding that HMRI was likely to succeed on the merits of its infringement suit, that HMRI would suffer irreparable injury, that a balancing of the equities and consideration of the public's interest weighed in favor of granting a preliminary

Contrary to Defendants' arguments here, the HMRI/Andrx Agreement did not resolve the pending patent claims; the only claims it resolved were Andrx's antitrust and unfair practice claims against HMRI. Rather than facilitating or fostering an expeditious resolution of the HMRI/Andrx patent infringement suit, the Agreement required Andrx to diligently prosecute its ANDA, the very act of infringement that triggered the HMRI/Andrx patent suit. The $10 million quarterly payments also created the incentive to pursue the litigation beyond the district court and through the appellate courts by extending those interim payments until entry of a final and unappealable order or judgment.

Likewise unavailing are Defendants' arguments that the Agreement merely protected HMRI's patent rights

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injunction in HMRI's favor, and that a Rule 65(c) bond was warranted in an amount equal to the amounts to be paid out under the HMRI/Andrx Agreement. Rather than seeking an injunction from the court, the parties agreed to keep the terms and existence of the Agreement confidential and further agreed that the Agreement, any drafts, or supporting documents were not to be introduced into evidence in the pending HMRI/Andrx patent action or any other litigation.

As one commentator has observed, "[w]ere one competitor to agree to pay, and to pay, another to leave a business in order to eliminate its competition, all would accept that ordinarily there had been a per se antitrust violation. A similar anti-competitive result can be achieved, in a more innocent-appearing manner, if the patent owner pays money, or gives an infringer some thing of value, to be subject to a patent injunction, especially if the injunction is broader than the claims. Ordinarily, consideration flows the other way; the infringer pays some amount to the patent owner for past infringement and then agrees to be subject to an injunction for the remaining life of the patent, or is granted a license." Robert J. Hoerner, *Antitrust Pitfalls in Patent Litigation Settlement Agreements*, 8 Fed. Circuit B.J. 113, 122 (Summer 1998). "If the patent owner pays the infringer, and if the infringer settles by accepting an injunction, or agrees to abandon the field, scrutiny is warranted." *Id.* at 123.

and provided Andrx with capital to invent around the '584 patent thus allowing Andrx an opportunity to enter the market sooner without the risk of patent liability. The Agreement barred Andrx from marketing not only the Andrx Product but also other bioequivalent or generic versions of Cardizem CD. *See* HMRI/Andrx Agreement at ¶ 2(A). Moreover, the Agreement defines the "Andrx Product" to include not only the product described in Andrx's original ANDA No. 74-752 but also the product described in any amendment or modification to Andrx's ANDA No. 74-752 not requiring withdrawal of that ANDA or submission of a new ANDA. *Id.* at ¶ 8(B)(iv). The Agreement thus barred Andrx from marketing non-infringing or potentially non-infringing versions of Cardizem CD, including the reformulated generic drug described in Andrx's September 11, 1998 prior approval supplement to its ANDA No. 74-752. Therefore, even assuming that the interim quarterly payments under the Agreement provided Andrx with capital to invent around the '584 patent, the terms of that Agreement still barred Andrx's entry into the market with that reformulated product.

Finally, the Court disagrees with Defendants' arguments that the Agreement's provisions providing Andrx with an option to obtain a license and thus market Cardizem CD without any risk of patent liability make it susceptible to rule of reason rather than *per se* analysis. The Agreement did provide Andrx with an opportunity to obtain a license from HMRI that, if exercised, would allow it to enter the market without the risk of patent liability both while the patent suit was still pending (in January 2000) and in the event Andrx ultimately lost the HMRI/Andrx patent suit. Consideration of the plain language of the HMRI/Andrx Agreement, its restraints and its likely effects, however, lead the Court to conclude

that the option to lease and other allegedly pro-competitive provisions of the Agreement do not preclude analysis under the *per se* rule. The Court is not convinced that the restraints embodied in the HMRI/Andrx Agreement are merely ancillary to the allegedly competition-enhancing provisions of that Agreement. Rather, the clear and unambiguous terms of the Agreement indicate that its main thrust was to have Andrx refrain from going to market with its generic version of Cardizem CD beyond the July 8, 1998 date when it could have entered the market, and to have Andrx continue the prosecution of its ANDA (the alleged infringing act) and not otherwise compromise its right to the 180-day exclusivity period (which would delay the entry by others with generic versions of Cardizem CD because, under the scheme of the Hatch-Waxman Amendments, these potential generic competitors would be forced to wait out this exclusivity period before obtaining FDA approval), and to have HMRI pay Andrx tens of millions of dollars as long as Andrx complied. The HMRI/Andrx Agreement, on its face, allocates the entire U.S. market for Cardizem CD and its bioequivalents to HMRI for the life of that Agreement. Accordingly, this Court concludes that it is a naked horizontal market allocation agreement and thus constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act and under the various state antitrust laws at issue here.

As the Supreme Court recently observed, it has "reiterated time and time again that '[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition.' Such limitations are per se violations of the Sherman Act." *Palmer*, 498 U.S. at 49 (quoting *Topco*, 405 U.S. at 608). The Court has further observed that, although § 1 of the Sherman Act "prohibits only agreements that *unreasonably*

restrain trade", "certain kinds of agreements will so often prove so harmful to competition and so rarely prove justified that the antitrust laws do not require proof that an agreement of that kind is, in fact, anti-competitive in the particular circumstances." *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133, 119 S. Ct. 493, 497 (1998). "An agreement of such a kind is unlawful *per se*." *Id.* (citing *Palmer* for the position that horizontal market allocation agreements are *per se* illegal). Accordingly, once the Court decides that an agreement is a kind that is unlawful *per se*, then it becomes irrelevant "whether or not [the Court] would decide this case the same way under the rule of reason." *Topco*, 405 U.S. at 609. Rather, "the Court has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because the are allegedly developed to increase competition." *Id.* at 610.

4. HMRI/Andrx Agreement's Effect on the Price of Cardizem CD

The Court rejects Defendants' arguments that the Court cannot consider the HMRI/Andrx Agreement's practical effect on the price of Cardizem CD. The anti-competitive effect of the HMRI/Andrx Agreement is obvious on its face. It restricted competition between HMRI, the brand-name drug manufacturer, and Andrx, the generic drug manufacturer; allocated the entire U.S. market for Cardizem CD and its bioequivalents to HMRI; and allowed HMRI to maintain or fix the price of Cardizem CD at a non-competitive level during the life of the Agreement. The courts have observed that "the per se ban on price fixing is not limited to an express horizontal agreement setting a uniform price for a product or service. Rather, the Supreme Court jurisprudence on the subject teaches that the courts must look at the

challenged horizontal agreement's practical effect on price and competition" and the Court "has ruled repeatedly that price fixing does not have to be direct in order to be actionable." *Saint Francis Hosp.*, 94 F. Supp. 2d 399, 412, 2000 WL 370531 at **10-12 (citing and discussing *Socony-Vacuum Oil Co.*; *Nat'l Soc'y of Prof'l Engineers v. United States*, 435 U.S. 679, 693-94 (1978) (where the Supreme Court observed that agreements that interfere with the setting of prices by "free market forces" are illegal on their face and further observed that a ban on competitive pricing does not require an elaborate industry analysis to demonstrate its anti-competitive character); and *Catalano v. Target Sales, Inc.*, 446 U.S. 643, 648-49 (1980) (where the Supreme Court similarly observed that, although there was no direct agreement as to prices, "an agreement to terminate the practice of giving credit . . . falls squarely within the traditional *per se* rule against price fixing")). *See also Palmer*, 498 U.S. at 48-49 (observing that "explicit agreement on prices to be charged or that one party have the right to be consulted about the other's prices" was not necessary to constitute an illegal *per se* price fixing agreement).

V. Conclusion

For the foregoing reasons, Plaintiffs' motions for partial summary judgment are **GRANTED**. The Court concludes that Defendants' September 24, 1997 Agreement constitutes a restraint of trade that is illegal *per se* under section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and under the various state antitrust laws at issue here.

By /s/ Nancy G. Edmunds
Nancy G. Edmunds
U.S. District Judge

Dated: 6/6/00

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-0113
Filed: December 12, 2000

In Re: CARDIZEM CD ANTITRUST LITIGATION;
MDL NO. 1278.

HOECHST MARION ROUSSEL, INC.,
ANDRX PHARMACEUTICALS, INC.,

Defendants-Petitioners.

B e f o r e :

DAUGHTREY and MOORE, *Circuit Judges*;
CARR, *District Judge.**

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* The Honorable James G. Carr, United States District Judge of the Northern District of Ohio, sitting by designation.

ORDER

The defendants in this multidistrict antitrust litigation petition under 28 U.S.C. § 1292(b) for leave to appeal interlocutory orders of the district court denying their motions to dismiss the plaintiffs' complaints and granting the plaintiffs' motions for partial summary judgment. The plaintiffs oppose the petition. The defendants have filed a reply.

A motion has been filed by the Pharmaceutical Research & Manufacturers of America (PhRMA) for leave to file an amicus-curiae brief in support of the defendants' petition. The plaintiffs oppose the motion. The issues and arguments raised by the PhRMA in their tendered brief are the same as those contained in the defendants' petition, and we find no cause for granting their motion. *See* Fed. R. App. P. 29(b)(2).

Section § 1292(b) provides for discretionary appellate review of interlocutory orders certified by the district court as involving "a controlling question of law as to which there is substantial ground for difference of opinion" and an immediate appeal of which "may materially advance the ultimate termination of the litigation . . . ." *See Cardwell v. Chesapeake & Ohio Ry. Co.*, 504 F.2d 444, 446 (6th Cir. 1974); *Kraus v. Board of County Road Comm'rs for Kent County*, 364 F.2d 919, 922 (6th Cir. 1966). Upon consideration of the facts and arguments presented, we conclude that this case is appropriate for interlocutory review. *See Good Investment Promotions, Inc. v. Corning Glass Works*, 493 F.2d 891 (6th Cir. 1974). *See also Hill v. Henderson*, 195 F.3d 671, 678 (D.C. Cir. 1999) (certification under 28 U.S.C. § 1292(b)

by the transferee court in a multidistrict case of potentially outcome determinative rulings is favored).

The defendants' § 1292(b) petition is **GRANTED**. The PhRMA's motion for leave to file an amicus-curiae brief is **DENIED.**

ENTERED BY ORDER OF THE COURT

By /s/ Leonard Green
Clerk

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 00-2483
Filed: July 24, 2003

IN RE: CARDIZEM CD ANTITRUST LITIGATION
LOUISIANA WHOLESALE DRUG CO., ET AL.

Plaintiffs-Appellees,

—v.—

HOECHST MARION ROUSSEL, INC. and
ANDRX PHARMACEUTICALS, INC, ET AL.,

Defendants-Appellants.

Before:

SILER and CLAY, *Circuit Judges*;
and OBERDORFER, *District Judge*

ORDER

The court having received a petition for rehearing en banc, and the petition having been circulated not only to the original panel members but also to all other active judges of this court, and no judge of this court having requested a vote on the suggestion for rehearing en banc, the petition for rehearing has been referred to the original panel.

The panel has further reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. Accordingly, the petition is denied.

ENTERED BY ORDER OF THE COURT

By /s/ Leonard Green
Leonard Green, Clerk

Section 1 of the Sherman Act

15 U.S.C. § 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

21 U.S.C. § 355. New Drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

* * * *

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

* * * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

* * * *

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the fac-

tual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

* * * *

(5)

* * * *

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

* * * *

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. * * * *

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

* * * *

35 U.S.C. § 154. Contents and term of patent; provisional rights

(a) In general.

(1) Contents. Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

* * * *

35 U.S.C. § 261. Ownership; assignment

Subject to the provisions of this title [35 USCS §§ 1 et seq.], patents shall have the attributes of personal property.

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States. * * * *

35 U.S.C. § 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

* * * *

(e)

* * * *

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

* * * *

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

* * * *

(4) For an act of infringement described in paragraph (2)

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

* * * *

35 U.S.C. § 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. * * * *

35 U.S.C. § 284. Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title. * * * *

STIPULATION AND AGREEMENT

Stipulation and Agreement, dated September 24, 1997, between Hoechst Marion Roussel, Inc. and Carderm Capital L.P. (collectively, HMRI) and Andrx Pharmaceuticals, Inc. (Andrx);

WHEREAS, HMRI is the holder of United States patent No. 5,470,584 ('584 Patent), which patent HMRI asserts covers the controlled release diltiazem hydrochloride formulation which is marketed in the United States under the trademark Cardizem® CD; and

WHEREAS, Andrx has developed a controlled release diltiazem hydrochloride formulation which it asserts is bioequivalent to Cardizem® CD and, pursuant to 21 U.S.C. § 355(j), has submitted and amended an abbreviated new drug application (ANDA) to the United States Food and Drug Administration (FDA) in order to obtain the right to sell that product (the Andrx Product) in the United States; and

WHEREAS, HMRI has filed a Complaint against Andrx in the United States District Court claiming that the Andrx Product infringes the '584 patent, which case is pending in the Southern District of Florida as Case Number 96-06121 (the Patent Infringement Action); and

WHEREAS, both parties recognize that until the issues of whether the Andrx Product infringes the '584 patent and whether the '584 patent is valid and enforceable are resolved in a final and unappealable order or judgment (Final Judgment) each party could take actions during the pendency of the Patent Infringement Action which could have significant financial repercussions; and

WHEREAS, HMRI believes that the market for diltiazem hydrochloride and the consumers of diltiazem

hydrochloride could be harmed in the event that an infringing or non-bioequivalent product were brought to market; and

WHEREAS, HMRI has asserted that it intends to seek an injunction barring the marketing, distribution or sale of the Andrx Product prior to the entry of Final Judgment on HMRI's claims in the Patent Infringement Action; and

WHEREAS, HMRI has also asserted that it intends to seek substantial damages and trebled damages for any marketing of the Andrx Product before the entry of Final Judgment; and

WHEREAS, Andrx recognizes that it could lose a substantial investment were it to move forward to market the Andrx Product following the date on which the FDA's approval of the Andrx Product under 21 U.S.C. § 355(j) becomes effective (FDA Approval) but before the entry of Final Judgment and were HMRI successful in obtaining an injunction blocking the distribution and sale of the product; and

WHEREAS, Andrx also recognizes that the damages could be potentially ruinous were Andrx to bring the Andrx Product to market and were HMRI to prevail in the Patent Infringement Action; and

WHEREAS, Andrx also believes that if it were to refrain from selling the Andrx Product until after Final Judgment is rendered in the Patent Infringement Action and it prevails in the Patent Infringement Action, then it will have lost substantial revenues from the Andrx Product; and

WHEREAS, Andrx is desirous of bringing a bioequivalent or generic form of Cardizem® CD to the market; and

WHEREAS, the parties intend to fully and vigorously litigate the infringement and validity issues underlying the Patent Infringement Action, but wish to reduce the risks and losses which could result from an adverse decision with respect to damages.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, and the mutual covenants set forth herein, the parties agree as follows:

1. *Effect of Recitals*:

The recitals set forth above are true and correct and are incorporated herein by reference.

2. *Obligation to Maintain Status Quo*:

(A). Pending the entry of Final Judgment, the parties agree to maintain the status quo with respect to the commercial sale of the Andrx Product in the United States. Andrx agrees not to commence the commercial sale of the Andrx Product or other bioequivalent or generic version of Cardizem® CD in the United States directly or indirectly until the entry of Final Judgment, or until it obtains a license from HMRI pursuant to paragraphs 5, 6, and 7 of this Stipulation and Agreement, or until Andrx receives the notice required by Paragraph 5 of this Stipulation and Agreement, whichever is the first to occur. Andrx further agrees that during the pendency of the Patent Infringement Action, it will diligently prosecute the ANDA for the Andrx Product and will not relinquish or otherwise compromise any right accruing thereunder or pertaining thereto.

(B). HMRI agrees not to seek further preliminary injunctive relief against Andrx in this litigation or otherwise until the entry of Final Judgment. HMRI further

agrees that for the period beginning on April 1, 1998 and ending upon the termination of this Stipulation and Agreement or the termination of any licensing agreement entered hereunder, whichever is later, HMRI will provide Andrx with a copy of any changes it proposes to the FDA with respect to the package insert and the immediate container label for Cardizem® CD within 10 days of the date upon which such proposed changes are transmitted to the FDA. HMRI further agrees that it will notify Andrx of any proposed changes which may be pending before the FDA as of April 1, 1998. HMRI further agrees to notify Andrx in writing of any labeling change which is approved by the FDA with respect to Cardizem® CD within 10 days of receiving notification of such approval.

(C). Andrx agrees that it will dismiss, without prejudice, its antitrust and unfair competition counterclaims in the Patent Infringement Action (including but not limited to counts III through VI and counts XI through XV of said counterclaim) within 30 days of the execution of this Stipulation and Agreement. Andrx further agrees that as between the parties to this Stipulation and Agreement, such dismissal shall be with prejudice as of the date that Final Judgment becomes effective, provided that HMRI has fully complied with the terms of this Stipulation and Agreement.

(D). Both parties agree that neither will apply to the court in the Patent Infringement Action for an order increasing or decreasing the thirty (30) month period provided for by 21 U.S.C. § 355(j)(4)(B)(iii).

3. *Lost Profit Payments*:

(A). For the purposes of this Stipulation and Agreement, the parties stipulate that the profits that Andrx

would have realized from the sale of the Andrx Product would be $100 million per year after FDA Approval.

(B). If Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, HMRI shall pay Andrx an amount, calculated at the stipulated rate of $100 million per year and prorated for fractions of a year, for the period beginning upon FDA Approval and ending on the date that Final Judgment becomes effective. (For the purposes of this Stipulation and Agreement, the Effective Date of Final Judgment shall mean the later of the date of final disposition in respect of said Final Judgment (or order, as the case may be) or the expiration of the period to appeal or seek review of said disposition, order or Final Judgment.) Said amount shall be reduced solely by an amount equal to the amounts actually paid to Andrx by HMRI pursuant to Paragraph 4(A) below.

(C). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the earlier of: (1) the date Andrx effects its first commercial sale of the Andrx Product; or (2) the date HMRI or its licensee effects its first commercial sale of a generic or bioequivalent form of Cardizem® CD, provided that the first such sale by HMRI or its licensee occurs after the expiration of the notice period described in Paragraph 5(B).

(D). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 3(B) above shall be the date upon which said license agreement becomes effective.

(E). Andrx shall prepare and forward an invoice for the amount due from HMRI pursuant to this Paragraph and that invoice shall be payable and paid to Andrx within 30 days of the date of the invoice.

4. *Interim Payments*:

(A). For the period beginning upon FDA Approval and ending on the Effective Date of Final Judgment, Andrx shall be entitled to receive nonrefundable interim payments from HMRI of $40 million per year, payable quarterly. Within 10 days after FDA Approval, HMRI shall pay to Andrx a prorated amount for the period between that effective date and the end of that calendar quarter. On the first day of each calendar quarter after that effective date, HMRI shall pay to Andrx the full $10 million quarterly payment due to Andrx under this Paragraph.

(B). In the event that HMRI provides Andrx with notice pursuant to Paragraph 5(B) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) shall be the date upon which the applicable written notice period described in Paragraph 5(B) expires or the date Andrx effects its first commercial sale of the Andrx Product, whichever is earlier.

(C). In the event that Andrx exercises its option to acquire a license pursuant to Paragraph 6 (A)(ii) of this Stipulation and Agreement, the end of the period described in Paragraph 4(A) above shall be the date upon which said license agreement becomes effective.

5. *License*:

HMRI hereby grants, and warrants it has the right to grant, to Andrx an irrevocable option to acquire a license (or sublicense as the case may be) to all intellectual property which HMRI owns or controls that Andrx may need to sell, market and distribute the Andrx Product in the United States, its territories and possessions, including the Commonwealth of Puerto Rico. (HMRI agrees that it shall not sell, assign or otherwise voluntarily divest itself of said intellectual property during the term of this Stipulation and Agreement in a way which would interfere with or otherwise frustrate Andrx's right to acquire a license under either Paragraphs 5 or 6 of this Stipulation and Agreement.) Such license shall be non-exclusive.

(A). In the event that Andrx previously has taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement, HMRI shall have no obligation to notify Andrx of HMRI's intention to either license said intellectual property to any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or through a subsidiary) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right.

(B). In the event that Andrx has not taken a license under Paragraphs 6(A)(i) or 6(A)(ii) of this Stipulation and Agreement and HMRI elects to either license said intellectual property to any other party (either directly or indirectly, including, but not limited to, an agreement not to enforce said intellectual property against the other

party) for the purposes of selling a bioequivalent or generic version of Cardizem® CD or utilize said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD in its own right, then HMRI shall give Andrx written notice prior to the date upon which the third party licensee is authorized to make its first commercial sale or the date of HMRI's first commercial sale as required in the following schedule:

(i). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or before July 1, 1998—360 days prior written notice is required.

(ii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises after July 1, 1998 and on or before December 31, 1998—180 days prior written notice is required.

(iii). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after January 1, 1999 and on or before March 31, 1999—120 days prior written notice is required.

(iv). If the date upon which the third party licensee is authorized to make its first commercial sale or HMRI's first planned sale arises on or after April 1, 1999 and on or before June 30, 1999—90 days prior written notice is required.

(v). If the date upon which the third party licensee is authorized to make its first commercial

sale or HMRI's first planned sale arises after June 30, 1999—30 days prior written notice is required.

(C). The notice provided in Paragraph 5(B) above shall identify, by name, the third party licensee or the HMRI entity authorized to sell a bioequivalent or generic version of Cardizem® CD and shall specify the date upon which the third party licensee is authorized to make its first commercial sale or the date HMRI's first commercial sale is contemplated.

(D). Except as expressly provided in this Stipulation and Agreement, HMRI expressly retains all rights under said intellectual property.

6. *Time to Exercise Option to Obtain License*:

(A). The option referred to in Paragraph 5 above must be exercised, if at all, at one of the three opportunities set forth below.

(i) By no later than the period beginning on the Effective Date of Final Judgment and ending 30 days thereafter.

(ii) In the event that Final Judgment is not entered before the earlier of:

(a) a date 18 months following FDA Approval; or,

(b) the date upon which FDA approval for a third party to make and market a bioequivalent or generic version of Cardizem® CD becomes effective.

Andrx may exercise said option at any time beginning on the earlier of these dates and end-

ing on the date 30 days after the Effective Date of Final Judgment.

(iii) In the event that HMRI notifies Andrx of its intent to license said intellectual property to any other party for the purposes of selling a bioequivalent or generic version of Cardizem® CD, or of its intent to use said intellectual property (directly or indirectly through a subsidiary or any other entity) for the purpose of selling its own bioequivalent or generic version of Cardizem® CD, Andrx may exercise said option at any time beginning on the date it receives said notification and ending on the Effective Date of Final Judgment.

(B). Except as regards the license fees and royalty rates set forth below, the terms of the license shall be negotiated in good faith by the parties and shall allow Andrx to sell the Andrx Product as a bioequivalent or generic version of Cardizem® CD. Andrx shall be authorized to sell the Andrx Product during such negotiations and prior to the execution of a formal license agreement.

7. *License Fee and Royalties*:

As set forth below, Andrx agrees to pay HMRI a license fee at the time it acquires a license pursuant to this Stipulation and Agreement as well as royalties based upon the "net receipts" based upon the sales of the licensed products. For the purpose of this Stipulation and Agreement and of any license entered into by the parties pursuant to this Stipulation and Agreement, the term "net receipts" shall mean gross receipts less deductions relating to returns, shelf stock allowances, discounts, rebates and similar adjustments.

(A). In the event that Andrx acquires the license pursuant to Paragraph 6(A)(i) of this Stipulation and Agreement, the license fee is $60 million and the royalty is 20% on net receipts.

(B). In the event that Andrx acquires the license pursuant to Paragraph 6(A)(ii) or Paragraph 6(A)(iii) of this Stipulation and Agreement, the initial license fee is $30 million and the royalty is 10% on net receipts collected prior to the Effective Date of Final Judgment.

(i). If Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, HMRI shall refund said license fee by paying to Andrx $30 million and shall refund all royalty payments made to HMRI by Andrx under the license within 30 days of the Effective Date of said Final Judgment, and the license shall be terminated on the Effective Date of Final Judgment.

(ii). Unless Final Judgment determines that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent, Andrx shall pay HMRI an additional license fee of $30 million within 30 days of the Effective Date of Final Judgment and thereafter pay HMRI a royalty of 20% on net receipts.

8. *Final Judgment and Termination*:

(A). In the event that HMRI dismisses the Patent Infringement Action prior to the Effective Date of Final Judgment, such dismissal shall be deemed to be as between the parties to this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe

said patent and said Final Judgment will be deemed to be effective on the date 90 days following the date upon which such dismissal becomes effective. HMRI agrees that such dismissal shall be with prejudice and shall eliminate HMRI's right to refile such an action pursuant to Paragraph 8(C). If Andrx has taken a license under either Paragraph 6(A)(ii) or 6(A)(iii) of this Stipulation and Agreement, Andrx's obligation to pay royalties under the license shall terminate as of the date such dismissal is entered (not the deemed Effective Date of Final Judgment), and Paragraph 7(B)(i) shall apply and Paragraph 7(B)(ii) shall not apply.

(B). It is understood by the parties that in addition to the specific obligations set forth in Paragraph 2 of this Stipulation and Agreement, Andrx agrees that it may not transfer, sell or assign any right to obtain a license pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or any rights granted to Andrx pursuant to a license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), and, subject to subparagraph (iv) below, Andrx may not, prior to the Effective Date of Final Judgment, withdraw the ANDA that it has submitted to the FDA for the Andrx Product.

(i). In the event that Andrx violates its obligations under Paragraph 2; transfers, sells or assigns any rights granted to Andrx by HMRI pursuant to Paragraphs 5 and 6 of this Stipulation and Agreement or pursuant to any license issued under said paragraphs to any other party without the express written consent of HMRI (a change in the ownership or control of Andrx's stock shall not require HMRI's consent), or, prior to the Effective Date of

Final Judgment, withdraws the ANDA that it has submitted for the Andrx Product, then Andrx shall pay HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated.

(ii). Before HMRI may seek termination of this Stipulation and Agreement and the return of monies paid to Andrx pursuant to this Subparagraph 8(B)(i), HMRI shall provide express written notice to Andrx specifying the obligation which, in HMRI's opinion, Andrx has not fulfilled, the specific manner in which each such obligation has not been fulfilled, and the specific conduct by Andrx that, in HMRI's opinion, will cure the asserted default. In the event that Andrx cures the alleged non-fulfillment identified by HMRI within 30 days of receiving such notice (or such other longer period as HMRI in writing expressly consents), such cure will be deemed full compliance (retroactive to the date of the first asserted default) and this Stipulation and Agreement will remain in full force and effect.

(iii). If Andrx has taken a license under either Paragraphs 6(A)(ii) or 6(A)(iii) of this Stipulation and Agreement, termination of this Stipulation and Agreement as contemplated under Paragraph 8(B)(i) shall not terminate any license previously granted to Andrx pursuant to Paragraph 5 and, with respect to license fees and royalty payments, Paragraph 7(B)(ii) shall apply and Paragraph 7(B)(i) shall not apply.

(iv). Nothing in this Stipulation and Agreement shall be construed as prohibiting or limiting Andrx's

right to amend or modify the ANDA that it has filed with respect to the Andrx Product so long as such amendment or modification shall not require the withdrawal of the existing ANDA and/or submission of a new ANDA and shall otherwise be consistent with Andrx's obligation to diligently prosecute its ANDA before the FDA as set forth in Paragraph 2 of this Stipulation and Agreement. For all purposes of this Stipulation and Agreement the term "Andrx Product" shall mean the product Andrx intends to sell pursuant to the ANDA on file with the FDA and as said ANDA may be amended consistent with this subparagraph.

(C). Notwithstanding any other provision of this Stipulation and Agreement, in the event that there is a final unappealable determination in the Patent Infringement Action that does not determine either (1) that the '584 Patent is valid and enforceable and the Andrx Product infringes said patent; or (2) that the '584 patent is invalid or unenforceable and/or that the Andrx Product does not infringe said patent, such determination shall be deemed to constitute, for all purposes in this Stipulation and Agreement, a Final Judgment that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent unless HMRI notifies Andrx in writing within 30 days of the date of such determination that it continues to believe that the Andrx Product infringes the '584 Patent and that it will seek to enforce the '584 patent by refiling its action at an appropriate time in an appropriate forum and refiles its action no later that 30 days following the later of either: (1) FDA Approval; or, (2) the date upon which the final unappealable determination referenced above in this Paragraph is entered. Andrx agrees that it will not seek to

block or otherwise frustrate HMRI's efforts to refile its action in this manner in a timely fashion provided that nothing herein shall be deemed to constitute a waiver by Andrx of any defenses, including the defense of preclusion, that it may have available in such refiled action. In the event HMRI provides the notice set forth above and refiles its action within the time frames herein established, such renewed action shall constitute the Patent Infringement Action for the purposes of the Stipulation and Agreement and the parties' respective obligations and rights under this Stipulation and Agreement shall continue uninterrupted and unimpaired as though no final, unappealable determination had been entered. In the event HMRI does not provide the notice set forth above or does not refile its action within the time frames herein established, Final Judgment shall be deemed to have been entered on the expiration of the period for HMRI to issue such notice, if it has not done so, or the expiration of the period in which it was required to refile such action if notice was provided, and for the purposes of this Stipulation and Agreement, such date shall be deemed as the Effective Date of Final Judgment. In the event that Final Judgment is deemed entered pursuant to this paragraph, it shall, as between the parties to this Stipulation and Agreement, constitute a final conclusive and unappealable determination that the '584 patent is invalid or unenforceable or that the Andrx Product does not infringe said patent.

(D). Notwithstanding any other provision of this Stipulation and Agreement, in the event that prior to a Court determining the issues of the validity of the '584 patent and whether the Andrx Product infringes that patent, Andrx in writing stipulates or, in open court and on the record, concedes that the '584 patent is valid and that the Andrx Product infringes said patent, Andrx shall

repay to HMRI an amount equal to the amount of all payments that have been paid to Andrx pursuant to this Stipulation and Agreement, and this Stipulation and Agreement shall be terminated.

9. *Use of Agreement*:

Except as otherwise required by law or as otherwise may be requested by the court in the Patent Infringement Action, the terms and existence of this Stipulation and Agreement shall be kept confidential. This Stipulation and Agreement and any drafts thereof or any documents or records pertaining thereto or information derived therefrom shall not be introduced into evidence in the Patent Infringement Action or any other litigation for any purpose.

10. *Effect of Agreement*:

The parties represent and warrant that this Stipulation and Agreement constitutes their valid and legally binding obligations and shall be binding upon and inure to the benefit of the parties hereto and their successors and assigns. Except as otherwise provided in Paragraph 8(B), this Stipulation and Agreement may not be assigned without the express written consent of the other party. However, nothing in this Paragraph or this Stipulation and Agreement shall restrict Andrx's right to assign its right to receive income under this Stipulation and Agreement.

11. *Applicable Law - Consent to Jurisdiction*:

The parties hereto expressly agree that all the terms and provisions hereof shall be construed under the laws of the State of Florida as now adopted or as may be hereafter amended, without giving effect to any conflict

of law or choice of law provision or rule. In the event of a dispute between the parties as to the interpretation, application or effect of this Stipulation and Agreement, the parties agree that any litigation arising out of such dispute shall be filed and venue shall be conclusively laid in the United States District Court for the Southern District of Florida, and both parties expressly consent to personal jurisdiction in that forum for the purposes of resolving said dispute.

12. *Entire Agreement*:

This Stipulation and Agreement constitutes the entire agreement of the parties hereto with respect to the matters set forth herein and supersedes any prior understanding or agreement, oral or written, with respect thereto.

13. *Nonpayment*:

Any amounts not paid when due shall thereafter bear interest at 18% per annum and all costs and expenses, including reasonable attorneys' fees, incurred in connection with the enforcement of this Stipulation and Agreement shall be paid to the prevailing party by the nonprevailing party, upon demand.

IN WITNESS WHEREOF, the parties hereto have caused this Stipulation and Agreement to be executed by their duly authorized representatives on the date first written above.

Hoechst Marion Roussel, Inc.

By /s/ Peter W. Ladell

Name Peter W. Ladell

Title Chief Operating officer

Andrx Pharmaceuticals, Inc.

By /s/ Chih-Ming J. Chen

Name Chih-Ming J. Chen, Ph.D.

Title President

Carderm Capital L.P.

By /s/ Dirk Kruse

Name Dirk Kruse

Title Authorized Representative

UNITED STATES COURT OF APPEALS
For the Eleventh Circuit

No. 00-2483

VALLEY DRUG COMPANY, LOUISIANA WHOLESALE DRUG COMPANY, INC. ET AL.,

Plaintiffs-Appellees,

—v.—

GENEVA PHARMACEUTICALS, INC., ABBOTT LABORATORIES

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Florida.

No. 02-12091.

Decided and Filed: September 15, 2003

Before:

TJOFLAT and ANDERSON, *Circuit Judges*;
STAFFORD, *District Judge*.

This case comes to us on interlocutory appeal from the district court's order granting plaintiffs' motion for partial summary judgment. The issue with which we are presented is whether the district court properly determined that two agreements among the defendants were per se violations of § 1 of the Sherman Act, 15 U.S.C. § 1. Because we conclude that the district court incorrectly applied the law, the order below will be reversed and the case remanded for further proceedings consistent with this opinion.

I. BACKGROUND

This is a private antitrust lawsuit, or rather numerous private antitrust lawsuits, brought against three pharmaceuticals manufacturers. The various cases asserting antitrust injury from the actions of the defendants have been consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. Plaintiffs basically assert that two agreements, one between defendant-appellant Abbott Laboratories ("Abbott") and defendant-appellant Geneva Pharmaceuticals ("Geneva") and another between Abbott and defendant Zenith Goldline Pharmaceuticals ("Zenith"),[1] entered into in 1998, violated the Sherman Act's prohibition against contracts

[1] Zenith came to a tentative settlement following the district court's order granting partial summary judgment and is not a party to this appeal.

in restraint of trade. Abbott, a manufacturer of the pioneer drug Hytrin, entered separate agreements with generic manufacturers Zenith and Geneva while those companies were pursuing FDA approval of generic versions of Hytrin and while embroiled in patent litigation with those companies. Because the facts of this case took place against a complex regulatory background, we will first describe the relevant regulatory context, then the facts of the case as they appear in the current procedural posture, and then the relevant procedural history.

A. *Regulatory Framework*

No new drug can be marketed or sold in the United States without approval from the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Applications for FDA approval can be filed in one of two ways: as a new drug application ("NDA") under § 355(b), or as an abbreviated new drug application ("ANDA") under § 355(j). A new drug application must include exhaustive information about the drug, including reports of safety and efficacy studies. *See* 21 U.S.C. § 355(b)(1).

Prior to 1984, the NDA was the only method of obtaining FDA approval of a new drug. Every applicant had to submit safety and efficacy studies, even if such studies had already been performed for identical drugs or drugs with identical active ingredients. Adding to this inefficiency was the fact that the conduct of safety and efficacy studies would, if the new drug was the subject of a patent, constitute infringement of that patent under 35 U.S.C. § 271(a).[2] In an effort to eliminate these twin

[2] "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

impediments to the introduction of generic drugs to the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The primary accomplishments of the Hatch-Waxman Act were the creation of the ANDA, allowing a new drug applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); modification of the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and allowing the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process, *see generally* 35 U.S.C. § 156.

Several of Hatch-Waxman's additions to 21 U.S.C. § 355 govern FDA approval of ANDAs in the face of patent claims by pioneer drug makers. NDA applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe.[3] If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues. *See* 21 U.S.C. § 355(c)(2). The FDA publishes this patent information, along with other information about the drug, in what is popularly known as the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A).

An ANDA applicant relying on the safety and efficacy studies filed with the application of a drug listed in the

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[3] Specifically, any patent claiming the drug or method of using the drug that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

Orange Book must make a certification with respect to each patent claiming the listed drug or a method of using the listed drug of which the applicant is aware. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The applicant must certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug. If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, *see* 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, *see* 21 U.S.C. § 355(j)(5)(B)(ii).

If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed, commonly called a "paragraph IV certification," several things happen. First, the applicant must notify the patent holder. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit for patent infringement[4] within 45 days of receiving this notice, the FDA automatically delays approval of the ANDA for thirty months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).[5]

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[4] It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). This definition of infringement was added by Hatch-Waxman to allow the invocation of the procedures described in the following paragraph of this opinion.

[5] The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45 day window

If the court hearing the infringement action declares the patent invalid or not infringed, this automatic delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if the court finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). If the court grants the patent holder a preliminary injunction prior to the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III).

The timing of FDA approval is affected by another provision of Hatch-Waxman in the event that a listed drug is subject to more than one paragraph IV certification. Approval of an ANDA that contains a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification. Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.[6] *See* 21 U.S.C. § 355(j)(5)(B)(iv). This delay-

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expires. The 30-month stay of FDA approval, however, will not be triggered.

[6] When the agreements at issue were entered into, the FDA regulations defined the relevant court decision triggering the end of the 30-month stay or the start of the first filer's 180-day exclusivity period as the decision of the appellate court hearing the infringement action against the first filer. This rule was challenged in court and held invalid by *TorPharm Inc., v. Shalala*, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sep. 15, 1997), *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998), *vacated on other grounds* (D.D.C. April 9, 1998) (30-month stay expires upon judgment of the district court holding the patent not

ing mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a patent on a pioneer drug a 180-day period during which it is the exclusive competitor of the pioneer manufacturer. This exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

B. *Factual History*[7]

1. Zenith's and Geneva's ANDAs

Abbott manufactures Hytrin, a brand-name drug with the active ingredient dihydrate terazosin hydrochloride.[8]

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infringed), and by *Mylan Pharms., Inc., v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000) (180-day exclusivity period triggered by judgment of the district court holding the patent invalid). Though the FDA was initially committed to continued adherence to the appellate judgment rule, *see* 62 Fed. Reg. 63,268 (Nov. 28, 1997), it dropped the rule following the *Mylan* decision, *see* 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (interim rule). The FDA now considers the 180-day exclusivity period to be triggered by any district court judgment holding the patent invalid, not infringed, or unenforceable, whether or not the judgment comes from the district court hearing the infringement suit against the first filer. *See Granutec, Inc., v. Shalala*, Nos. 97-1873 & 97-1874, 1998 WL 153410, *8-9 (4th Cir. April 3, 1998) (unpublished, table decision reported at 139 F.3d 889) (endorsing the FDA's position that, if the successful defense requirement is invalid, the court decision triggering the 180-day exclusivity period is the decision of any district court). *See also Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) (reversing district court's denial of an injunction to require the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). *See post* at n.12 for a discussion of the successful defense requirement.

[7] The facts are largely uncontested by the parties.

[8] Terazosin hydrochloride is a crystal. Dihydrate terazosin hydrochloride is a particular crystalline polymorph of terazosin

Hytrin is used to treat hypertension and enlarged prostate, and has been a very successful product for Abbott. Abbott obtained FDA approval of its NDA for Hytrin in 1987 and has held a number of patents related to terazosin hydrochloride over the years. Its first patent, issued in 1977, covered the basic terazosin hydrochloride compound. *See Abbott Labs. v. Novopharm Ltd.*, Nos. 96-C-611 & 95-C-6657, 1996 WL 131498, *1 (N.D. Ill. March 15, 1996). That patent has since expired, though Abbott has been issued other patents for various crystalline forms of the compound and various methods of using and preparing the compound.

Geneva filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents. Abbott brought infringement suits under 35 U.S.C. § 271(e), invoking the 30-month stay of FDA approval of Geneva's ANDAs. On April 29, 1996, Geneva filed two additional ANDAs based on Hytrin, one for a capsule form of terazosin hydrochloride and one for a tablet form[9], making paragraph IV certifications with respect to the relevant patents. Within 45 days of receiving notice of Geneva's paragraph IV certifications, Abbott filed an infringement suit based on the submission of the tablet ANDA, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's patent number 5,504,207 ("the '207 patent").[10] In the suit,

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hydrochloride. The opinion will refer to terazosin hydrochloride and its polymorphs simply as terazosin hydrochloride unless greater specificity is appropriate.

[9] The active ingredient in these two drugs is anhydrous terazosin hydrochloride.

[10] The '207 patent, issued on April 2, 1996, claims a method of preparing anhydrous terazosin hydrochloride. The patent is due to expire in October of 2014.

Geneva admitted infringement but contested the patent's validity. Apparently through oversight, Abbott failed to file an infringement suit based on the submission of the capsule ANDA. FDA consideration of that ANDA, therefore, proceeded unhindered, and Geneva's capsule ANDA was approved in March of 1998. When Abbott was notified of this approval, it began efforts to amend its complaint to allege that Geneva's terazosin hydrochloride capsule infringed the '207 patent.

Zenith, meanwhile, filed an ANDA for a terazosin hydrochloride drug[11] in June of 1994, making a paragraph IV certification with respect to Abbott's Hytrin patents. Abbott was issued a patent claiming forms of terazosin hydrochloride on May 2, 1995, patent no. 5,412,095 ("the '095 patent"), and another on April 2, 1996, the '207 patent. Abbott timely filed this patent information with the FDA, which then required Zenith to amend its ANDA to make a certification with regard to these newly listed patents. Zenith resisted, hoping to avoid the 30-month stay of approval and the 180-day delay of approval based on Geneva's earlier-filed ANDAs.[12] Instead of certifying, Zenith brought suit

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[11] The active ingredient of this drug is anhydrous terazosin hydrochloride.

[12] Prior to 1998, the FDA applied the "successful defense" requirement to ANDA filers hoping to take advantage of the 180-day exclusivity period. A subsequently-filed ANDA would only have its approval date delayed by 180 days if the first-filer had successfully defended against an infringement suit. *See* 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994) (adopting successful defense regulation as a final rule, codified at 21 C.F.R. § 314.107). If Zenith's ANDA were ready for approval before Geneva successfully defended Abbott's infringement suit, then the ANDA would be approved without the 180-day delay. If Zenith were forced to make a paragraph IV certification with respect to Abbott's '095 and '207 patents, however,

against Abbott in an attempt to force Abbott to delist its '095 and '207 patents, relieving Zenith of the obligation to certify with respect to those patents, and seeking a declaration that its terazosin hydrochloride drug did not infringe those patents. Zenith's suit alleged that Abbott listed the '095 and '207 patents knowing that the patents did not claim Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. *See Zenith Labs. v. Abbott Labs.*, No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

2. The Agreements

The agreements challenged by the plaintiffs arose against this backdrop. On March 31, 1998, Abbott and Zenith entered an agreement dismissing Zenith's delisting claims and Abbott's infringement counterclaims ("Zenith Agreement"). In the Zenith Agreement, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin hydrochloride product Zenith might market would infringe these patents. Zenith agreed not to sell or distribute any pharmaceutical product containing any

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Abbott could invoke the 30-month stay of approval, giving Geneva more time to defend Abbot's infringement action against it.

The successful defense requirement was eventually held to be an unreasonable interpretation of the Hatch-Waxman Act by two courts of appeals. *See Mova Pharm. Corp. v. Shalala*, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1069-70 (D.C. Cir. 1998); *Granutec*, 1998 U.S. App. LEXIS 6685, 1998 WL 153410, at *6-7. The Mova court enjoined the FDA from enforcing the regulation, and the FDA dropped the requirement effective November 10, 1998. *See* 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (interim rule).

form of terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's patent no. 4,215,532 (the '532 patent) expired.[13] Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents claiming terazosin. In return, Abbott agreed to a payment schedule according to which Abbott would pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. Abbott agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.

Abbott entered an agreement with Geneva on April 1, 1998 ("Geneva Agreement"). According to the Geneva Agreement, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a court judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid. This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to

[13] The '532 patent claims dihydrate terazosin hydrochloride, the active ingredient in Hytrin. That patent expired on February 17, 2000.

oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA. In return, Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal. Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date. If Abbott exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.

3. Termination of the Agreements

The district court hearing Abbott's infringement suit against Geneva handed down its decision on September 1, 1998. *Abbott Labs. v. Geneva Pharms., Inc.*, Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). The court held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent, *see* 35 U.S.C. § 102(b). 1998 U.S. Dist. LEXIS 13864, 1998 WL 566884 at *7. Abbott appealed to the Federal Circuit, which affirmed on July 1, 1999. 182 F.3d 1315 (Fed. Cir. 1999). Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S. Ct. 796 (2000).

The Agreements did not terminate on their own terms, however. The parties terminated the Agreements on August 13, 1999, apparently in response to an FTC investigation of those Agreements. The FTC action resulted in a consent settlement. *See Matter of Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), *also available at* http://www.ftc.gov/os/2000/05/c3945.do.htm.

C. *Procedural History*

All class action and individual antitrust plaintiffs filed a joint motion for summary judgment that the Agreements were *per se* illegal under § 1 of the Sherman Act on February 18, 2000. The district court issued an order granting the motion on December 13, 2000. Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted on April 19, 2002.

D. *The Order Granting Summary Judgment*

The December 13, 2000, Order granting plaintiffs' motion for partial summary judgment concluded that the Agreements were *per se* violations of § 1 of the Sherman Act. The Order characterized the Agreements as geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements.

The court found that on the eve of the Agreements,

> both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," and the 30-month stay on its generic tablet proposal was set

> to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.

In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1345-46 (S.D. Fla. 2000). Despite being poised to enter the market, however, "Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs . . . ." *Id.* at 1348-49.

The court identified four elements of the Agreement with Geneva that were anticompetitive: (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated; (2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated. The court identified three anticompetitive elements of the Agreement with Zenith: (1) Zenith's agreement to dismiss its delisting suit; (2) Zenith's promise not to aid any other entity's challenge to the validity of Abbott's terazosin patents; and (3) Zenith's promise not to market a generic terazosin product until the Agreement terminated. The essence of the Agreements, the court concluded, was to "dissuade[ ] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period [and] eliminate the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim . . . ." *Id.* at 1349.

Despite holding the Agreements *per se* unlawful, the court nonetheless entertained, and rejected, the defendants' arguments that the Agreements were either pro-

competitive or benign.[14] Defendants argued that the Agreements eliminated the "substantial legal and financial risks" that accompany market entry while patent disputes remain unresolved. This justification was rejected for three reasons. First, the Agreement with Geneva was unnecessary to avoid these risks, because Geneva's unilateral decision to forego entry would achieve the same result. Second, the Agreement with Geneva did not resolve the patent litigation; "in fact, it tended to prolong that dispute to Abbott's advantage." *Id.* at 1350. The litigation was prolonged by the provisions extending the Agreement until the patent dispute was finally resolved, including Supreme Court review, and by Geneva's promise to aid Abbott in any motion seeking to extend the 30-month stay of FDA approval of Geneva's tablet ANDA. Finally, the court rejected the argument that the provision of the Agreement permitting Geneva to enter the market if Abbott elected to suspend its payments was pro-competitive. Although the court may have been willing to "infer that this clause was a catalyst for competition if Geneva paid Abbott for it, [ ] the suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for ter-

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[14] Defendants also argued that the Agreements were immune from antitrust liability under the *Noerr-Pennington* doctrine, *see United Mine Workers v. Pennington*, 381 U.S. 657, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961); that the Agreements were not subject to *per se* treatment because of their novelty; and that the Agreements could not have anti-competitive effects because independent regulatory prohibitions prevented market entry by Geneva and Zenith until at least August of 1999. The court rejected these arguments, as well. The defendants do not raise their *Noerr-Pennington* or ineffective restraints arguments on appeal.

azosin hydrochloride products is patently unreasonable." *Id.* at 1351. The court did not analyze any potentially efficiency-enhancing effects of the Agreement with Zenith, concluding that the Agreement "would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market." *Id.*

Defendants argued that because the Agreement with Geneva was analogous to an interim patent settlement and the Agreement with Zenith terminated the litigation between Zenith and Abbott, the court should treat the Agreements as patent litigation settlements. The court rejected this argument as well, concluding that the Agreement with Geneva did not resolve Abbott's infringement suit and that the termination of litigation between Zenith and Abbott "was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products." *Id.* at 1353. Even if the Agreements were patent litigation settlements, the court held, such settlements were not immune from *per se* analysis. *Id.*

E. *Issues Appealed*

On appeal, Abbott and Geneva argue that the district court erred in concluding that the Agreements were per se violations of § 1 of the Sherman Act and that genuine issues of material facts remain in dispute.

Appellants argue that courts lack sufficient experience with agreements of the kind at issue to draw the conclusion that "history and analysis have shown that in sufficiently similar circumstances the rule of reason unequivocally results in a finding of liability." *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir. 1991) (quotation and citation omitted). Appellants also argue that there are pro-competitive justifications

for the Agreements that warrant analysis under the rule of reason. Appellants argue that genuine issues of material fact are in dispute with regard to these potential procompetitive effects. Finally, Appellants argue that the Agreements are patent litigation settlements that must be analyzed under the rule of reason unless it is shown that the settlements were "sham."[15]

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. *Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1242 (11th Cir. 2002). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the evidence in the light most favorable to the non-movant, resolving all reasonable doubts and drawing all reasonable inferences in that party's favor. *Bailey*, 284 F.3d at 1243.

III. DISCUSSION

Section 1 of the Sherman Act prohibits "every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations . . . ." 15 U.S.C. § 1. It is understood that the ban on "contract[s] in restraint of trade" means only unreasonable restraints, *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S. Ct. 275,

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[15] Indeed, all of appellants' arguments rely primarily on the circumstance that the Agreements arose in the context of patent litigation.

279 (1997), that is, restraints that impair competition, *Chicago Board of Trade v. United States*, 246 U.S. 231, 238, 38 S. Ct. 242, 244 (1918). Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive, that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement. *State Oil*, 522 U.S. at 10, 118 S. Ct. at 279; *Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332, 344, 102 S. Ct. 2466, 2473 (1982). These agreements are labeled "*per se*" violations. Regardless of terminology, the ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue. *National Collegiate Athletic Ass'n v. Bd. Regents Okla. Univ.*, 468 U.S. 85, 103, 104 S. Ct. 2948, 2962 (1984). The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties. *See California Dental Ass'n v. FTC*, 526 U.S. 756, 779-81, 119 S. Ct. 1604, 1617-18 (1999), *NCAA*, 468 U.S. at 103-04, 104 S. Ct. at 2961-62.

The district court focused on the agreements by Geneva and Zenith not to enter the market with FDA-approved (or approval pending) generic terazosin drugs, holding that this exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore *per se* illegal. We begin our discussion by addressing this exclusionary effect of the Agreements.

A.

An agreement between competitors to allocate markets is, as the district court noted, clearly anticompetitive. Such an agreement has the obvious tendency to diminish

output and raise prices. When a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50, 111 S. Ct. 401, 403 (1990) (per curiam) (agreements not to compete within certain territorial limits are obviously anticompetitive); *United States v. Topco Assocs.*, 405 U.S. 596, 608, 92 S. Ct. 1126, 1133-34 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a *per se* violation of the Sherman Act, with no purpose other than reducing competition).

If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. For reasons explained below, and in light of the fact that all parties seem to agree that the ANDAs that were the subjects of the infringement suits infringed Abbott's '207 patent, we reject the district court's characterization of the instant Agreements as illegal *per se*. We believe any such characterization is premature without further analysis of the kind suggested in this opinion. Because the market allocation characterization was central to the district court's conclusion that the Agreements in their entireties are *per se* violations of § 1 of the Sherman Act, we will reverse the grant of summary judgment.

A patent grants its owner the lawful right to exclude others. *See* 35 U.S.C. §§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S. Ct. 2601, 2623 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting

by the patented invention."). This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. *Bonito Boats, Inc., v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51, 109 S. Ct. 971, 977-78, 103 L. Ed. 2d 118 (1989); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981). The exclusionary right cannot be exploited in every way—patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example, *see United States v. New Wrinkle, Inc.*, 342 U.S. 371, 72 S. Ct. 350 (1952)—but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, *see, e.g., In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1209 (2d Cir. 1981); or grant exclusive territorial licenses carving up the United States among its licensees, *see* 35 U.S.C. § 261. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class. *Gen. Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 58 S. Ct. 849 *aff'd on reh'g*, 305 U.S. 124, 59 S. Ct. 116 (1938) (approving a license restricting the licensee's sales to non-commercial customers). Such arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, but these anticompetitive tendencies do not render them in violation of the Sherman Act.

The above discussion illustrates the point that a patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agree-

ments as territorial market allocations agreements, the district court did not consider that the '207 patent gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride until October of 2014, when it is due to expire.[16] To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.

Zenith's agreement not to market an infringing generic terazosin hydrochloride drug terminated, by its own terms, when either another generic manufacturer marketed a terazosin product and any exclusivity period expired or Abbott's '532 patent expired in February of 2000. The effect of the Zenith Agreement on the production of Zenith's infringing terazosin product appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired. Geneva's agreement not to market an infringing terazosin product terminated at the earliest of (1) a final, unappealable judgment holding the '207 patent invalid; (2) the marketing of a terazosin product by another generic manufacturer; or (3) the expiration of the '532 patent. The effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent. The '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from

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[16] The '207 patent was, of course, declared invalid on September 1, 1998, a judgment affirmed on January 10, 2000. The antitrust consequences of this subsequent invalidation will be addressed below.

marketing its terazosin hydrochloride products during this period.[17]

With respect to the foregoing aspects of the two Agreements' exclusionary effects, which were the foundation of the district court's characterization of the Agreements as market allocation agreements, these are at the heart of the patent right and cannot trigger the *per se* label. [18] Unlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. As one court has concluded, "when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249

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[17] We say "may" because we do not hold that the '207 patent *would* have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. We mean only that these are among the considerations that the district court should address on remand. We do note that appellees have not at this stage argued that Abbott would have been unable to obtain such relief.

[18] Appellees argue that the Agreements have broader exclusionary tendencies in that they also prohibited the marketing of non-infringing terazosin products, prohibited Geneva from marketing infringing products beyond the date a district court held the '207 patent invalid, and prohibited Geneva from waiving its 180-day exclusivity period. As we explain below, these prohibitions may be beyond the scope of Abbott's lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation. Our point thus far is that appellees have failed to prove that appellants should face *per se* antitrust liability for treble damages for the failure of Zenith and Geneva to market admittedly infringing products when no court had declared Abbott's patent invalid or unenforceable at the time of the Agreements.

(E.D.N.Y. 2003). Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute per se violations of the antitrust laws must be reversed.

While our holding at this early stage of the litigation is appropriately narrow, the decision below and the arguments of the parties invite our discussion of several matters that promise to be relevant on remand. We first discuss appellees' argument that the antitrust analysis need not consider Abbott's patent rights because the '207 patent was declared invalid. We then discuss appellees' argument that the lawful right of exclusion does not include the right to pay competitors not to produce infringing products. Finally, we offer several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis.

B.

The individual *Sherman Act* plaintiffs-appellees argue that because the '207 patent was declared invalid after the Agreements were entered into, Abbott never had any patent rights and our antitrust analysis need not consider the '207 patent. We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into. *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); *SCM Corp.*, 645 F.2d at 1207. At the time the Agreements were entered into, no court had declared Abbott's '207 patent invalid, and the appellees have advanced no argument

other than mere invalidity.[19] We hold that the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.

The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim, *see Walker Process Equip., Inc., v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179, 86 S. Ct. 347, 351 (1965) (Harlan, J., concurring), or as a limited exception to the general rule that markets should be free from barriers to competition, *see id.*, 382 U.S. at 176, 86 S. Ct. at 350; *United States v. Line Material Co.*, 333 U.S. 287, 309, 68 S. Ct. 550, 561 (1948); *id.*, 333 U.S. at 310, 68 S. Ct. at 562. Appellees' argument implies that this defense is unavailable with respect to the Agreements because the '207 patent was subsequently held invalid.

The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office. *Walker Process*, 382 U.S. at 177, 86 S. Ct. at 350 (considering a monopolization claim against a patentee for suing to enforce a patent allegedly procured by fraud). Good faith procurement furnishes a complete defense to the antitrust claim. *Id.* Justice Harlan's concurrence explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken

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[19] That is, appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be.

into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws:

> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.

382 U.S. at 179-80, 86 S. Ct. at 351-52. This approach is commonly used by courts considering the intersection of patent law and antitrust law. *See, e.g., SCM Corp.*, 645 F.2d at 1203-06 (considering antitrust claims against a patentee for acquiring and refusing to license various patents); *Handgards, Inc., v. Ethicon, Inc.*, 601 F.2d 986, 992-93 (9th Cir. 1979) (considering a monopolization claim against a patentee for asserting a patent it

allegedly knew to be invalid). A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of the two:

> It is commonly said . . . that the patent and antitrust laws necessarily clash . . . At the same time, the two regimes seek the same object: the welfare of the public . . . Antitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.

H. Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999) ("Hovenkamp") (citations and quotations omitted). *See also* D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 748 n.1 (2002) ("It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1352 (Fed. Cir. 1999) ("The patent and antitrust laws are complementary in purpose in that they each promote innovation and competition . . . .") (citation omitted).

Employing this approach, we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether

enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.[20] This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation. *See Ciprofloxacin*, 261 F. Supp. 2d at 256 (expressing concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and development); *cf. Walker Process*, 382 U.S. at 180, 86 S. Ct. at 352 (Harlan, J., concurring) (permitting antitrust liability based on a showing mere invalidity "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damages suits").

There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be

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[20] The cost and complexity of most patent litigation is a familiar problem to the court system. *See, e.g., Blonder-Tongue*, 402 U.S. at 331-32 & 334-38, 91 S. Ct. at 1444 & 1445-48 ; *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1475-76 (Fed. Cir. 1998) (Rader, J., dissenting) (discussing claim construction); *Matter of Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, *166-67 & *239-40 (F.T.C. June 27, 2002), *also available at* http://www.ftc.gov/os/caselist/d9297.htm. *See also* Crane, 54 Fla. L. Rev. at 757. The cost savings of settlement, both to the parties and to the public, are equally widely-recognized. *See Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure. *Cf. Walker Process*, 382 U.S. at 179-180, 86 S. Ct. at 351 (Harlan, J., concurring) (noting that exposing patentees to antitrust liability for the assertion of a patent known to have been procured by fraud "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure"). In this regard we note that some lower courts have extended *Walker Process* to permit antitrust claims against patentees for the anticompetitive effects of infringement lawsuits when the antitrust claimant proves that the patentee knew that the patent was invalid, *Handgards*, 601 F.2d at 994-96, or knew that the patent was not infringed, *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876-77 (Fed. Cir. 1985), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).[21] To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.

C.

The class action plaintiffs-appellees argue that the patent right does not include the right to pay infringers, with the implication that any exclusion resulting from payment rather than judicial enforcement is not pro-

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[21] Similarly, it has been suggested that the "sham" exception to the antitrust immunity afforded by the *Noerr-Pennington* doctrine is or may be available also to antitrust plaintiffs seeking to pierce the patent immunity. *See Independent Services Organizations*, 203 F.3d at 1326-27. Because the parties have not briefed such potential exceptions to the patent immunity from antitrust liability, we do not address them at this time.

tected from per se antitrust liability by the patent laws. Our discussion with regard to the important role played by settlement in the enforcement of patent rights leads us to reject this argument as well. Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a *per se* violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. *See Ciprofloxacin*, 261 F. Supp. 2d at 251-52 (discussing the asymmetries of litigation risk created by Hatch-Waxman and rejecting the argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis); Crane, 54 Fla. L. Rev. at 774 (discussing the dynamics of settlement before the alleged infringer has entered the market).

We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. *See Aro Corp.*, 531 F.2d at 1372. To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a *per se* rule

would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

It may be that the size of the payment to refrain from competing, sometimes called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent[22], particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity.[23] Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. Given the asymmetries of risk and large profits at stake, even a patentee confident in

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[22] For example, the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid. *See* discussion in Part B, *supra*.

[23] For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

the validity of its patent might pay a potential infringer a substantial sum in settlement. *See, e.g., Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 196, 234 (settlement agreements under which a patentee paid an infringer $49.1 million to acknowledge the validity of a patent, and at least $398 million for the infringer to remain off the market, though the patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times).

Another possibly suspicious characteristic of the payments to Geneva is their structure (i.e., tying their duration to the length of the litigation), which, as the district court noted, may have given Geneva an incentive to delay resolution of the infringement suit.[24] But if the payments were in furtherance of the seemingly reasonable purpose of compensating Geneva for any lost profits during the course of litigation (much like a bond posted as part of a preliminary injunction), it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.

We recognize that the Sixth Circuit appeared to take the opposite view in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.").[25] When the exclusionary power of a patent is implicated, however, the antitrust analysis

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[24] Neither appellees nor the district court have offered any similar suspicions with regard to the structure of payments under the Zenith Agreement.

[25] The terms of the agreements at issue in the *Cardizem CD* case were similar to the terms of the Agreements in this case.

cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." *Studiengesellschaft*, 670 F.2d at 1128. As the above discussion indicates, we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws[26], nor do we think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent.

Because these matters were given scant attention in the district court, considering the court's primary con-

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[26] The Sixth Circuit seems to have placed considerable reliance upon the generic's agreement to delay entering the market in exchange for exit payments, although it may also have been influenced by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent. For example, the Sixth Circuit mentioned the effect of the agreements regarding the 180-day exclusivity period as well, and its reference to the district court opinion in that case might reflect some reliance on the restriction on non-infringing products. *See Cardizem CD*, 332 F.3d at 907-08; *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 705 (E.D.Mich. 2000). However, the Sixth Circuit opinion did not purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not. *Cf. Cardizem CD*, 105 F. Supp. 2d at 701 ("The anticompetitive effects of [the] patent are likewise not at issue."). To the extent that the Sixth Circuit suggests that a settlement of patent litigation was a *per se* violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree. We believe that the potential exclusionary power of the patent must first be considered.

clusion that the Agreements were market division agreements like those in *Palmer* and Topco, these questions have not been explored. We simply note them here to explain our conclusion that the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abbott's potential exclusionary rights under the '207 patent.

D.

Our discussion so far has been limited to the exclusionary effects of the instant Agreements to delay entrance into the market, the subsequent invalidation of the patent, and the mere fact of exit payments. To the extent that these or other effects of the Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to *per se* antitrust condemnation.[27] From the preceding discussion, we conclude that deciding the antitrust implications of these exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of "achieving a suitable accommodation between the differing policies." *Walker Process*, 382 U.S. at 179, 86 S. Ct. at 351 (Harlan, J., concurring).

As alluded to earlier, however, *see supra* at ___ n.18 (M/S at 26, n.18), the instant Agreements are not con-

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[27] Application of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated. Rule of reason and *per se* analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.

fined to matters involving restrictions on infringing products, exit payments, and a subsequent court decision declaring the patent invalid. Appellees also challenge other provisions of the Agreements, such as those prohibiting the marketing of "any" generic terazosin product; Geneva's agreement not to waive its 180-day exclusivity period; and Geneva's agreement not to come to market until a final, unappealable judgment of invalidity rather than on a district court judgment. These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof. Because these considerations require a different analytic framework than that applied by the district court and advocated by the parties on appeal, it is appropriate to remand to the district court to apply an appropriate framework derived from this decision, and the arguments of the parties and the facts developed on remand. To aid in the development of an appropriate framework, we offer the following observations.

We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee. "The precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise." *Line Material*, 333 U.S. at 300, 68 S. Ct. at 557. *See also New Wrinkle*, 342 U.S. at 378, 72 S. Ct. at 353 ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing] when the licenses are used, as here, in the scheme to restrain."); *United States v. Masonite Corp.*, 316 U.S. 265, 277, 62 S. Ct. 1070, 1077 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A

patent affords no immunity for a monopoly not fairly or plainly within the grant.").

The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law[28] and consideration of the extent to which the Agreements reflect a reasonable implementation of these. Appellants, for example, contend that certain provisions of the Geneva Agreement are analogous to a consensual preliminary injunction and stay of judgment pending appeal. To evaluate this claim, the provisions of this Agreement should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of Abbott's obtaining such protections. *Cf.* Hovenkamp at ¶ 2046 ("some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation").

Any provisions of the Agreements found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act.[29] *Standard Oil Co., Ind., v. United States*, 283 U.S. 163, 175, 51 S. Ct. 421, 425-26, 75 L. Ed. 926 (1931) (recognizing that cross-licensing agree-

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[28] We express no view at this time on what role the FDA's regulation of market entry might play in the appropriate antitrust analysis.

[29] Courts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protection. *See Line Material*, 333 U.S. at 307, 68 S. Ct. at 560 (holding a patent pooling agreement that fixed the prices at which licensees would sell the patented product *per se* illegal); *Masonite*, 316 U.S. at 274, 62 S. Ct. at 1076 (holding a price-fixing agreement among patentees and their licensees *per se* illegal).

ments and a division of royalties could be used to monopolize or fix prices and examining the evidence to assess the potential for anticompetitive effects as a result of the agreements at issue). The appropriate analysis of the market effects of such provisions may depend on the nature of the provision challenged. It may be that some challenged provisions are so obviously anticompetitive that they can be condemned as illegal on the evidence so far adduced, or it may be that the tendencies of some challenged provisions cannot be confidently predicted without further inquiry.

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment. What is required, rather, in an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Cal. Dental, 526 U.S. at 780-81, 119 S. Ct. at 1618.[30] If on remand the court should conclude that part, but not all, of the provisions of the Agreements violate the Sherman Act, it may also be helpful to identify with specificity which provisions or combination of provisions are illegal[31] and the nature of the anticompetitive effects of

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[30] Because the appellants' arguments supporting the application of the rule of reason rely primarily on the circumstance that the Agreements arise out of patent litigation, and because the determination of the appropriate analysis should await the inquiries to be made on remand, we decline at this time to address the issue further. We note, however, that the application of the rule of reason is not synonymous with exhaustive factual inquiry. "[S]ome rule-of-reason cases can be disposed of merely on the basis of the parties' arguments and, more often, on the basis of a limited summary judgment record." Hovenkamp, ¶ 1508.

[31] This is not to suggest that the provisions should be considered in isolation; agreements that are anticompetitive when consid-

those provisions or combinations in order to aid subsequent determinations on causation and antitrust injury. Finally, the particular circumstances of this case and the arguments of the parties on remand may demonstrate other relevant considerations.

IV. CONCLUSION

The district court's order granting partial summary judgment is REVERSED and this case is REMANDED for further proceedings consistent with this opinion.[32]

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ered in isolation (such as covenants not to compete) can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition. *See Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729, 99 L. Ed. 2d 808, 108 S. Ct. 1515, 1523 & n.3 (1988), *Polk Bros.*, 776 F.2d at 189. We simply suggest that careful consideration of individual provisions may be helpful should it appear that the Agreements are unlawful only in part.

[32] All pending motions are DENIED.

Supreme Court, U.S.
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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., AND RITE AID CORP., *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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QUESTION PRESENTED

Whether the courts below properly concluded that it is *per se* unlawful under Section 1 of the Sherman Antitrust Act for a pharmaceutical patentee to pay a competitor $89 million to keep its competing, FDA-approved generic product off the market during the pendency of patent litigation.

CORPORATE DISCLOSURE STATEMENT

Respondent CVS Meridian, Inc. is a wholly owned subsidiary of CVS Corporation.

Respondent Eckerd Corp. is a wholly owned subsidiary of J.C. Penney Co., Inc.

Respondent The Stop and Shop Supermarket Co. is a wholly owned subsidiary of Ahold USA, Inc.

Respondents Rite Aid Corporation, Albertson's, Inc., The Kroger Co., Walgreen Co., and Hy-Vee, Inc. have no parent corporations and there are no publicly traded companies that own 10% or more of their stock.

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This case involves "a multi-million dollar cash payment [by Hoechst Marion Roussel ("HMR")] in consideration for forbearance by Andrx [Pharmaceuticals, Inc. ("Andrx")] from selling on the market a product that it was ready and able to sell at a price lower than that charged by HMR for [its] patented product." Pet. App. at 31a. The United States Court of Appeals for the Sixth Circuit characterized the Agreement between HMR and Andrx ("the Agreement") as "a plain vanilla horizontal agreement to restrain trade," *id.*, that was a *per se* violation of federal antitrust laws. Labels aside, the court considered the regulatory context in which the Agreement arose, analyzed the exclusionary power of HMR's patent, and considered and rejected the procompetitive justifications offered by the defendants. However denominated, the Court of Appeals' analysis was a correct and straightforward application of the settled law of this Court; it does not require review by this Court.

Review should also be denied because (a) the Circuit conflict asserted by Andrx involves only two Courts of Appeals, and cases involving broader issues of the interplay between pharmaceutical patents and antitrust law have not had the appellate and scholarly analysis necessary to a fully-considered review by this Court; (b) the opinion as to which Andrx seeks review is interlocutory; and (c) the type of agreement at issue here is peculiar to the pharmaceutical industry and, due to recent significant legislative changes, is not likely to recur even in that industry.

COUNTER-STATEMENT OF THE CASE

On average, the price of generic drugs is less than half that of their brand-name counterparts. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, 31 (July 1998). In 1984, Congress enacted the Hatch-Waxman Act.[1]

1. That Act is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (*codified* as amended at 21 U.S.C. § 355).

"One of [its] primary goals was to increase the availability of lower-cost generic drugs." *Id.* at 27. To expedite the approval process and hence such drugs' availability, the Act allows a manufacturer seeking to market a generic bioequivalent of an FDA-approved drug to file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). Allowed to rely upon the safety and effectiveness data submitted to the FDA by the manufacturer of the pioneer drug, *id.*, the generic manufacturer can substantially shorten the time required to gain approval of the generic bioequivalent.

On September 22, 1995, Andrx filed an ANDA seeking FDA approval to manufacture and market a generic bioequivalent of Cardizem CD. Cardizem CD is a once-a-day prescription drug manufactured and sold by HMR for the treatment of hypertension and angina. Although the patent on the active chemical ingredient in Cardizem CD expired in November 1992, HMR has a patent, issued in November 1995, on the controlled release formulation which it marketed in the United States under the trademark Cardizem CD.

As an ANDA applicant, Andrx was required to make one of four certifications regarding the pioneer drug's patent status. 21 U.S.C. § 355(j)(2)(A)(vii). Andrx filed a "Paragraph IV Certification," certifying that the patent on the Cardizem CD pioneer drug is invalid or would not be infringed by the generic drug. As required by the statute, Andrx notified HMR, the patent owner, of the ANDA filing and Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B)(i). In response, in January 1996, HMR commenced a patent infringement action against Andrx, thus triggering a statutory 30-month waiting period before the ANDA could receive the FDA's final approval and Andrx could begin selling its generic drug. *See id.* at § 355(j)(5)(B)(iii). The principal issue in that action was whether Andrx's proposed generic drug had dissolution specifications claimed in HMR's patent.

Andrx filed a counterclaim against HMR asserting antitrust and unfair competition claims on the ground that HMR's patent suit was a "sham" – that no reasonable litigant could expect success on the merits of the claim. *See* Pet. App. at 7a. While Andrx asserted that HMR's patent was invalid, the principal thrust of its defense was that its product did not infringe the HMR patent. Pet. App. at 6a-7a. Andrx asserted to the patent court that it would bring its product to the market as soon as it received final FDA approval. Pet. App. at 7a.

On September 17, 1997, the FDA tentatively approved Andrx's generic drug, meaning that the drug would receive final approval upon the expiration of the 30-month stay on July 9, 1998. Andrx in fact received final FDA approval on July 9, 1998 and was therefore authorized to begin selling its generic version of Cardizem CD as of that date. HMR never sought a preliminary injunction to bar Andrx from selling the generic drug. In recent proceedings in this case, the district court has ruled that there is ample evidence that, but for the Agreement between HMR and Andrx, Andrx would in fact have launched its generic product in July 1998. *See In re Cardizem CD Antitrust Litigation,* 99 MDL 1278, Order No. 80, slip op. at 49-50 (E.D. Mich. Nov. 13, 2003) (Edmunds, J.) ("*In re Cardizem,* Order No. 80").

Because Andrx was the first manufacturer to file an ANDA with a Paragraph IV Certification for a generic bioequivalent of Cardizem CD, Andrx received a statutory 180-day period of market exclusivity before other ANDAs for generic versions of the same pioneer drug could be approved by the FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Congress enacted the 180-day provision specifically in order to create a powerful incentive for generic drug manufacturers to challenge the validity of patents on brand-name pharmaceuticals. *Pharmachemie B.V. v. Barr Labs., Inc.,* 276 F.3d 627, 629 (D.C. Cir. 2002). Until very recent legislative changes (*see infra* section IV), the 180-day period began to run when the first ANDA applicant either began

selling the generic drug or obtained a judgment that the patent is invalid or not infringed, whichever occurred first. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is a valuable commodity that can be sold or waived for substantial consideration, as would happen if, for example, the first-filer was not prepared to launch but a subsequent ANDA filer was. *See, e.g., Granutec, Inc. v. Shalala*, 1998 U.S. App. LEXIS 6685, at *16 (4th Cir. Apr. 3, 1998); *Mylan v. Shalala*, 81 F. Supp. 2d 30, 42 (D.D.C. 2000).[2]

On September 24, 1997, less than 10 days after Andrx received tentative FDA approval for its generic drug, Andrx and HMR entered into the Agreement at issue here. Under the Agreement, Andrx agreed not to market any generic version of Cardizem CD until a final and unappealable judgment of invalidity or non-infringement was entered in the infringement case. Pet. App. at 97a-99a. Thus, in the absence of such a judgment, Andrx agreed not to market a generic version of Cardizem CD (a) even after Andrx received final FDA approval; (b) even after the automatic 30-month prohibition provided by the Hatch-Waxman Act had expired; and (c) even though the district court hearing the patent case, far from granting a preliminary injunction, had not even been asked by HMR to issue one. By its express terms, this contractually mandated delay in marketing the generic drug applied even if the drug infringed no patent right held by HMR. Pet. App. at 99a-100a. The Agreement also barred Andrx from transferring to another generic manufacturer Andrx's right to the 180-day exclusivity. Pet. App. at 99a. The Agreement thus created a "bottleneck" that prevented not only Andrx, but also any other generic manufacturer of Cardizem CD, from coming onto the market.

In exchange for Andrx's promise to keep generic products off the market, HMR agreed to make non-refundable payments

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2. The FDA will respect such transactions in granting final approval to generic manufacturers that otherwise would be excluded from the market. *See, e.g., Granutec, Inc.*, 1998 U.S. App. LEXIS 6685, at *16.

of $40 million per year to Andrx. Pet. App. at 102a. Additionally, HMR agreed to increase the payments retroactively to $100 million per year if Andrx ultimately prevailed in the infringement suit. Pet. App. at 100a–101a. In the Agreement, HMR and Andrx expressly characterized these payments as compensation for Andrx's "lost profits," Pet. App. at 100a–101a, thus acknowledging that, absent the Agreement, Andrx would in fact have entered the market in July 1998; if Andrx would not have entered, there would have been no lost sales on which Andrx lost profits.

Andrx complied fully with the Agreement and did not market the generic drug even after final FDA approval on July 9, 1998. In June 1999, the FTC began an investigation into the Agreement. Private plaintiffs also filed antitrust claims challenging the Agreement. *See, e.g., Kroger Co., et al. v. Hoechst Marion Roussel, Inc., et al.*, No. 99-6533 (S.D. Fla. filed Apr. 26, 1999). Soon thereafter, HMR and Andrx decided to terminate the Agreement. In conjunction with this decision, HMR dismissed its patent infringement suit and paid Andrx, the alleged infringer, an additional $49 million on top of the $40 million that it had already paid. *See* Pet. App. at 18a. This brought the total payment to the pro-rated equivalent of the annual $100 million payment required if Andrx won the patent action. *See* Pet. App. at 101a. In late June 1999, eleven months after receiving final FDA approval, Andrx finally began marketing a generic version of Cardizem CD.

Plaintiffs/Respondents are chain drugstores that are either direct purchasers of Cardizem CD or the assignees of such purchasers.[3] Plaintiffs assert that but for the Agreement and the payment by HMR to Andrx of at least $40 million per year, Andrx would have brought its generic product to market when

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3. The various cases challenging the Agreement were consolidated for pretrial proceedings in the Eastern District of Michigan by the Judicial Panel on Multidistrict Litigation. *In re Cardizem CD Antitrust Litig.*, MDL-1278 (E.D. Mich.) (Edmunds, J.).

it received FDA approval in July 1998 and that it would have done so at a price lower than that of the patented Cardizem CD sold by HMR. The suits allege that the Agreement unlawfully protected HMR from competition not only from Andrx but also from other potential generic competitors because of the 180-day exclusivity "bottleneck." *See* page 4, *supra.*

On May 11, 2000, the United States District Court for the Eastern District of Michigan granted Plaintiffs' motion for partial summary judgment, ruling that the Agreement constituted an illegal market allocation agreement and was *per se* illegal. Pet. App. at 34a-82a. The district court then certified the issue for interlocutory appeal under 28 U.S.C. § 1292(b).

The Sixth Circuit accepted the appeal and affirmed the district court's holding that the Agreement was unlawful. Pet. App. at 20a-21a. Characterizing the Agreement as unlawful *per se*, the Court of Appeals nevertheless conducted a careful analysis of the statutory and regulatory framework, found that the Agreement provided exclusion to HMR beyond that provided by the patent, and considered and rejected each of the procompetitive justifications proffered by the defendants. Pet. App. at 17a-21a.

The district court has subsequently denied Andrx's motion for summary judgment on the issue of whether Andrx's conduct caused injury to Plaintiffs; in doing so, the court found that there is very substantial evidence that, absent the unlawful Agreement, Andrx would in fact have entered the market in July 1998 – eleven months before its actual entry. *In re Cardizem,* Order No. 80, at 49-50. An estimated 3-week trial of the *CVS Meridian* plaintiffs' claims is scheduled to commence on April 12, 2004. *In re Cardizem,* Scheduling Order No. 49 (E.D. Mich. Dec. 3, 2003) (Edmunds, J.).

REASONS FOR DENYING THE PETITION

I. THE PETITION SHOULD BE DENIED BECAUSE THE SIXTH CIRCUIT DECISION REFLECTS THE STRAIGHTFORWARD APPLICATION OF SETTLED PRECEDENT OF THIS COURT.

There is nothing remarkable or even noteworthy about the Court of Appeals' conclusion that it is *per* se unlawful for one competitor to pay another to stay out of the market. The Court concluded that the Agreement is "at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." Pet. App. at 18a. That conclusion is consistent with more than a century of jurisprudence holding agreements between actual or potential competitors to allocate territories or customers to be unlawful *per se* under Section 1 of the Sherman Act. *See, e.g., Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *United States v. Topco Assoc.*, 405 U.S. 596, 608-09 (1972); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899).

Of course, the Court of Appeals was required to take account of the fact that HMR asserted a right to exclude Andrx's product under the patent law. A patent owner cannot be subject to antitrust liability merely for exercising whatever power is given to him by the patent to exclude others from making, using, or selling his invention. But when the patent owner exercises exclusionary power *beyond* that conferred by the patent, he and his co-conspirators are fully subject to the antitrust law, including, where the nature of the restraint warrants, the *per se* rule. This has been settled law for decades. *See, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377-78 (1952); *United States v. United States Gypsum Co.*, 333 U.S. 364, 400-01 (1948); *United States v. Line Material Co.*, 333 U.S. 287, 314-15 (1948); *see also id.* at 319 (Douglas, J., concurring) (when patent owner

agrees on price with competitor, "[h]e then gets not a benefit inherent in the right of exclusion, but a benefit which flows from suppression of competition by combination with his competitors"). And it is consistently recognized as the governing standard today. *See, e.g., Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990).

A. *The Court of Appeals' Analysis*

In a straightforward application of these principles, the Court of Appeals held that the Agreement clearly enabled HMR to wield exclusionary power beyond that conferred by the patent.

The patent conferred exclusionary power on HMR in three ways:

- *First*, it gave HMR the ability to exclude generics by filing an infringement suit that triggered the Hatch-Waxman Act's automatic 30-month exclusion. That exclusionary period expired in July 1998 and was simply not in force in the July 1998-June 1999 period during which the Agreement kept Andrx from marketing its generic product.

- *Second*, the patent also gave HMR the ability to seek a preliminary injunction from the patent court. This was a mere threat; Congress did not give patent holders an absolute right to pretrial exclusion. In order to exclude allegedly infringing products during the pendency of an infringement action, a patent holder must satisfy the criteria for entry of a preliminary injunction, including a showing that his patent is likely to be found valid and infringed and that the public will not be harmed. Absent such a showing, the alleged infringer has a "right to compete." *See, e.g., Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (denying preliminary injunction and permitting pretrial entry).

- *Third*, the patent gave HMR the ability to threaten to collect damages against Andrx for pretrial sales if the patent court subsequently found these sales to have been infringing.

This was also a mere threat; Congress gave patent holders a rebuttable, but not conclusive, presumption of validity, and Congress placed the burden on the patent holder to prove infringement.[4] In the 40 Hatch-Waxman cases that have been litigated to final judgment, the generic manufacturer has been found not to have infringed a valid patent in 29 of them. FTC, *Generic Drug Entry Prior to Patent Expiration* at 19-20, (July 2002) (available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

Against that background, the Court of Appeals held that the HMR patent did not create an "'impenetrable' legal impediment to Andrx's production and sale of its FDA-approved generic product." Pet. App. at 31a. Indeed, the Court found that if the "independent durability of [HMR's] patent and the validity

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4. If HMR had simply threatened Andrx with the possibility of an injunction and/or liability for damages, HMR would have been exercising the power inherent in the patent, and there would be no issue of antitrust liability. No one asserts that it is unlawful for patent litigants to settle a patent case based on the strength of the patent as perceived by the litigants. For example, the alleged infringer may exit the market in exchange for the patent holder's waiver of accrued damages, and patent litigants may settle the case by the patent holder granting a license to the alleged infringer. Herbert Hovenkamp, et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1739-42 (2003); Keith Leffler, Christopher Leffler, "*Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*," 2 ABA Economics Committee Newsletter 26, 33 (Spring 2002). In such cases, the patent holder is merely wielding whatever exclusionary power the patent actually confers, and the sole source of the exclusion is the perceived power of the patent.

Andrx's assertion that the FTC staff has sought *per se* condemnation of "delayed licenses" *absent exclusion payments*, Pet. at 15, is simply wrong. The assertion is not supported by Andrx's citations. In fact, the FTC staff has not sought condemnation of delayed licenses *absent exclusion payments* even under the rule of reason. *In re Schering Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Decision, December 8, 2003).

of its infringement claim" had been sufficient on their own to exclude Andrx from the market, then HMR "would not have paid [Andrx] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 32a. Rather than granting to HMR an absolute right to exclusion, the patent law and HMR's patent merely created in Andrx a "fear of damages in the patent infringement litigation," *id.* at 25a, a fear that may or may not have prompted Andrx, acting "unilaterally, and legally [to refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 32a. HMR's payments to Andrx gave to HMR that which the patent law did not; "the Agreement *guaranteed* to HMR that its only potential competitor at that time, Andrx, would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval." *Id.* at 17a-18a (emphasis added).

In short, HMR did not procure Andrx's exclusion from the market merely by exercising the statutorily-approved exclusionary power of the patent. Instead, HMR procured Andrx's exclusion *by adding to that power the extra-statutory exclusionary power of $89 million*. HMR confronted Andrx not only with the "stick" of the power of the patent – the prospect of being subjected to an injunction or having to pay damages – but also with the "carrot" of multimillion-dollar payments. Citing precisely this analysis from the Plaintiffs' brief below, the Court of Appeals succinctly and definitively held: "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Pet. App. at 19a.[5]

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5. In the Agreement, Andrx also agreed to refrain from selling products that did not even arguably infringe HMR's patent. *See* Pet. App. at 99a. As to these plainly non-infringing generic versions of Cardizem CD, HMR had no patent power at all, but rather presented

(Cont'd)

The Court of Appeals noted that, given the obviously anticompetitive nature of the Agreement, the defendants' proffered justifications were irrelevant as a matter of law. Pet. App. at 20a (*citing Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332 (1982)). The Court nevertheless considered and rejected all of the procompetitive justifications offered by HMR and Andrx for their unlawful agreement. Specifically, "the Agreement cannot fairly be characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation." Pet. App. at 19a. The Court noted that the rejection of these procompetitive justifications was "explained in greater detail in the district court's opinion." *Id.* at 18a-19a. (*citing* 105 F. Supp. 2d at 700-05, which is Pet. App. 75a-81a).

For example, the district court rejected the defendants' contention that HMR's payments provided Andrx with capital to invent around the HMR patent and therefore come to market sooner than was otherwise possible. Pet. App. at 78a-79a.

(Cont'd)

Andrx *solely* with the power of $40 million per year. A more naked, blatantly unlawful agreement is hard to imagine. *United States v. United States Gypsum Co.*, 333 U.S. 364, 400 (1948); *Dole Refrig. Co. v. Kold-Hold Mfg. Co.*, 185 F.2d 809, 816 (6th Cir. 1950); *United States v. Crown Zellerbach Corp.*, 141 F. Supp. 118, 126 (N.D. Ill. 1956) ("any attempt to prohibit competition from unpatented goods carries the patentee beyond the immunity of the patent law"); *United States v. National Lead Co.*, 63 F. Supp. 513, 524 (S.D.N.Y. 1945). The Agreement also provided an ironclad guarantee against competition not only from Andrx, but also from *any* generic manufacturer. As noted, the Agreement prohibited Andrx from relinquishing or assigning its 180-day period of exclusivity under the Hatch-Waxman Act, a period which began to run only after the Agreement-delayed date on which Andrx began to market the drug. This Agreement-created "bottleneck" prevented all other generic manufacturers from coming to market with a generic product. Pet. App. at 8a; s*ee also Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1067 (Fed. Cir. 1998); David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food and Drug L. J. 321, 335 (2000).

The Court noted that the Agreement prevented Andrx from coming to market even with the reformulated product that HMR's payments allegedly helped it to produce. *Id.* And although it was unnecessary for the court to reach these issues, we note that defendants did *not* assert that Andrx *needed* to use the payments from HMR, that HMR was the only source of such development funds, or that Andrx needed anywhere near $89 million to create the reformulated product. Indeed, HMR paid Andrx $49 million after Andrx had already reformulated the product. Pet. App. at 9a.

In short, the Court of Appeals conducted a detailed analysis of the Agreement against the relevant statutory and regulatory background, concluded that the $89 million payment allowed HMR to obtain guaranteed pretrial exclusion that neither the patent law nor the Hatch-Waxman Act provided, and considered and rejected each of the procompetitive justifications offered by the defendants. It is irrelevant that the Court of Appeals used the "per se" label to describe its careful analysis, the fact is that the analysis was "meet for the case." *California Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999).

B. *Professor Hovenkamp's Analysis*

Concluding that agreements such as that at issue here should be found "presumptively unlawful," prominent commentators have endorsed the analysis employed by the Court of Appeals here. *See* Hovenkamp, 87 Minn. L. Rev. 1759; Carl Shapiro, Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391, 396-402 (2003). These commentators note that Congress did not, as it might have done, grant to patent holders an automatic right to pretrial exclusion or grant to them a conclusive presumption of validity. The reward actually granted by Congress to patent holders for their innovation is only *some probability* (less than 100%) of being able to exclude competitors. Payments by the patent holder such as those involved in this case bolster the probability of exclusion from something less than 100% to 100%; thus such payments, in

every case, impermissibly add to the exclusionary power of the patent. Professor Hovenkamp explains:

> [A] patent is not a right to exclude, but rather a right to try to exclude. Indeed, a significant number of patents that make it to court are ultimately held invalid or not infringed. The legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. **What the pharmaceutical patentees who agree to exclusion payments seek is something more – a guaranteed insulation from competition, without the risk that the patent is held invalid.** [Intellectual property] policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.

Hovenkamp, 87 Minn. L. Rev. at 1761-62 (emphasis added). As is readily apparent, this is the same substantive analysis employed by the Court of Appeals.

C. *The FTC's Analysis*

The same type of analysis was also recently endorsed by a unanimous Federal Trade Commission in *In re Schering-Plough Corporation*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003) ("*In re Schering-Plough*") (page citations are to page numbers available on Westlaw version). While the FTC asserted that its analysis was one conducted under the rule of reason, it readily acknowledged that the label attached to such analysis is largely a question of "semantics" and that what matters is the substance of the analysis actually employed. *Id.* at 9-10 n.17.

Like the Court of Appeals, the FTC began its analysis by observing that neither the patent law nor the Hatch-Waxman Act grants to a patent holder an absolute right to exclusion.

The FTC noted that "antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework." *Id.* at 16. Accordingly,

> We cannot assume that [the patent holder] had a right to exclude . . . generic competition for the life of the patent any more than we can assume that [the generic manufacturer] had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that [the patent holder's] payment to [the generic manufacturer] was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

Id. at 17.[6]

The FTC held that common sense and economic theory demonstrate that "the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 15. It held that any substantial payment made by the patent holder is therefore anticompetitive. *Id.*

Like the Court of Appeals in the instant case, the FTC also considered and rejected the defendants' proffer of procompetitive justifications. In particular, the FTC considered a justification that a "'cash-starved' generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer." *Id.* at 19. The FTC ruled that such a justification cannot be accepted unless the defendants "explain why the [patent holder] was the best source for the necessary funds; [and] demonstrate that the up-front support actually resulted in an entry date earlier than would be expected without it." *Id.* at 20. The FTC noted that, in any event, such an alleged procompetitive justification "could not

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6. "We focus on the state of the world as it was perceived by the parties at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out." *Id.* at 18.

justify a payment of any amount close to the $60 million." *Id.* at 20. *A fortiori*, such a proffered procompetitive benefit could not justify the $89 million payment at issue here.

Like the Court of Appeals, the FTC fired a shot across the bow of others that may be considering exclusion payments. The FTC held that in future cases the Commission may apply a "more truncated analysis," *id.* at 20, and seek disgorgement of profits, *id.* at 41 n.113.

The FTC's decision does include one additional strand of analysis that is absent from the Court of Appeals' decision. The FTC began its analysis by finding as a fact that the patent holder had market power. *Id.* at 11-15. It was perhaps appropriate for the FTC, as an administrative agency examining the issue for the first time, to engage in a detailed analysis of market power. The reality, however, is that it is obvious that a patent holder will not pay a generic manufacturer to refrain from entering the market unless the patent holder in fact has market power. *See* Hovenkamp, 87 Minn. L. Rev. at 1757-58; *see also* Robert Bork, *The Antitrust Paradox*, 269 (Free Press 1993) ("Very few firms that lack power to affect market prices will be sufficiently foolish to enter into conspiracies to fix prices. The fact of agreement defines the market."). If a patent does not confer upon its holder the ability to charge an above-competitive price, the patent holder has no reason to pay a potential competitor to refrain from entering the market; entry of an additional competitor will not have any effect on the market price. Thus, despite the fact that the FTC conducted a market power inquiry and the Court of Appeals did not, such an inquiry is entirely unnecessary on the facts as presented here.

* * * * *

The analyses of the Sixth Circuit, Professor Hovenkamp, and the FTC each conclude that payments by the patent holder to the potential generic entrant are unlawful because neither the

patent law nor the Hatch-Waxman Act grants to patent holders a right to automatic exclusion. By making substantial payments to a potential entrant to refrain from entering, the patent holder obtains exclusion beyond that provided by the patent or the regulatory framework. Absent procompetitive justifications – and there are none here that are valid – agreements embodying such payments are unlawful under the Sherman Act.

That conclusion is particularly clear with respect to a pharmaceutical patent holder's right to *pretrial* exclusion. In the Hatch-Waxman Act, Congress granted to holders of such patents 30 months of guaranteed exclusion pending resolution of a lawsuit initiated by the patent holder. 21 U.S.C. § 355(j)(5)(B)(iii). This automatic exclusion – which in original versions of the legislation was for only 18 months – was part of the complex balancing by Congress between the rights of patent holders and those of consumers and generic manufacturers. *See* Alfred Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 398-407 (1999) (reviewing legislative history). Congress expressly withheld automatic exclusion when the patent holder failed to meet the statutory criteria or when the 30 months expired. On what conceivable basis could an antitrust court then permit the patent holder to pay his competitor, as HMR paid Andrx, for exclusion in months 31 to 42?

Of course, the patent court might have subsequently found Andrx's pretrial generic sales to have been infringing. This Court, however, has rejected attempts to justify cartels on the ground that they were necessary to suppress "illegal" competition. *See, e.g., FTC v. Ind. Fed. of Dentists*, 476 U.S. 447, 465 (1986) ("That a particular practice may be unlawful is not, in itself, a sufficient justification for collusion among competitors to prevent it"); *Fashion Orig. Guild, Inc. v. FTC*, 312 U.S. 457, 468 (1941) (prevention of illegal competition is no defense to Section 1 claim). If competition that is *concededly* illegal is still protected by the antitrust laws, then competition

that is only *possibly* illegal – competition in the shadow of potential patent infringement liability – is even more clearly entitled to that same protection. As noted by Professor Shapiro, "Congress should set the rules governing what type of competition is permitted in the shadow of patent litigation and then private firms should live within those rules. Competitors should not be permitted to enter into private agreements that eliminate competition otherwise permitted by Congress." Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 Antitrust 70, 73 (2003).[7]

II. THE PETITION SHOULD BE DENIED IN ORDER TO AWAIT FURTHER CONSIDERATION OF THE ISSUE BY OTHER LOWER COURTS AND SCHOLARS.

Pointing to the Eleventh Circuit's decision in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), Andrx asserts that there is a "split in the circuits" that justifies review by this Court. Pet. at 1. But the split is between only the Sixth and Eleventh Circuit decisions, both of which were rendered on interlocutory review. Moreover, even the conflict between those two Courts is over a very narrow point.

Both Courts agree that: (1) the proper antitrust inquiry is whether the patent holder exceeded the exclusionary power of the patent; *see* Pet. App. at 19a and 148a-149a, and (2) the first step in that analysis is to determine the nature and scope of the exclusionary right actually granted by Congress in the patent law. *See* Pet. App. at 19a and 149a. The Courts' analyses (and conclusions) diverge because the Sixth Circuit carefully delineated the precise nature of a patent holder's right to pretrial exclusion of allegedly infringing competition.

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7. Thus, contrary to Andrx's assertion, Pet. at 24, the Court of Appeals' decision does not "promote infringing competition." When neither the Hatch-Waxman Act nor a preliminary injunction prohibits competition, the Court's decision appropriately protects competition that is merely *alleged* to be infringing.

See Pet. App. at 19a. The Eleventh Circuit did not; its *entire* analysis on the critical first step consisted of the bald and oversimplified assertion that "a patent grants its owner the lawful right to exclude others." Pet. App. at 133a. The Eleventh Circuit did not consider the significance of the fact that the patent law does *not* grant an absolute right to a preliminary injunction. Nor did the Eleventh Circuit address the fact that Congress in the Hatch-Waxman Act expressly limited the right to automatic exclusion to 30 months.

Given the Eleventh Circuit's erroneous delineation of a patent holder's right to pretrial exclusion,[8] it is unsurprising that the Court held that the patent holder's payment was not necessarily beyond the exclusionary power of the patent. Pet. App. at 135a-136a. *If*, arguendo, a patent granted an *absolute* right to pretrial exclusion, then the antitrust laws should indeed be indifferent to the fact that the patent holder was foolish enough to pay for that to which he was already absolutely entitled.

It is highly unlikely that another court of appeals will make the fundamental error committed by the Eleventh Circuit. Indeed, this case and the Eleventh Circuit case are the only pending cases involving payments to preclude *pretrial* competition. All of the other pending cases involve exclusion payments made in connection with *final settlement* of patent litigation. *See, e.g., In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003); *In re Schering-Plough,* FTC Docket No. 9297. Thus, none of those cases will involve the issue that divided the

8. The Court's consequently flawed antitrust analysis is not different in kind from a court's announcement that because a patent "grants its owner the lawful right to exclude others," the holder may lawfully pay a competitor to stay out of the market in years 21 and 22 – even though a *properly delineated* "right to exclude" shows that the temporal scope of the patent is only 20 years. It is simply not enough to say that a patent grants a "right to exclude;" a proper antitrust analysis depends upon a correct understanding of the nature and contours of that right.

Sixth and Eleventh Circuits – the proper delineation of the right to *pretrial* exclusion under the patent law.

To the extent that other pending cases involve the broader general issue of the proper interplay between patent and antitrust law in the pharmaceutical arena, the federal courts are only now beginning to develop a body of law on the appropriate antitrust analysis. Even if the issue is ultimately deemed important enough to be addressed by this Court, the Court should have in front of it the fully developed analysis of the appellate courts. At the moment, that analysis simply is not complete.

For instance, in the most procedurally advanced case, *In re Tamoxifen Citrate Antitrust Litigation*, 277 F. Supp. 2d 121 (E.D.N.Y. 2003), appeal pending, No. 03-7641 (2d Cir. June 20, 2003),[9] the patent holder both made a relatively modest payment ($21 million) and granted the generic manufacturer a 9-year license to bring a cheaper version of the branded drug onto the market. The district court held that plaintiffs had not alleged that, absent the $21 million payment, the license terms would have been any more favorable to consumers. *Id.* at 136-37. The district court therefore dismissed the antitrust complaint for, among other things, failure to allege antitrust injury. *Id.* at 137-38. Thus, on review, the Court of Appeals may not even reach the question whether the agreement was unlawful.

Another case from the Second Circuit, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), may ultimately yield a more complete court of appeals analysis because the exclusion payment there was $398 million and the district court has required the parties to present a full rule of reason analysis. *Id.* at 257-58. But discovery in that case has only recently closed and motions for summary judgment are not due until May 28, 2004.

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9. The opening brief has not yet been filed in the Court of Appeals.

The very recent FTC decision in *In re Schering-Plough Corp.* will presumably be appealed to a court of appeals. Depending on the relative pace of review, an appellate decision could be issued roughly contemporaneously with that of the Sixth Circuit after the April 12, 2004 trial scheduled in this case.[10]

Contrary to Andrx's suggestion, Pet. at 13, the current activity in the federal courts on these issues strongly supports denying the Petition. Because there are only two pending cases involving payments for pretrial exclusion, review by this Court is not warranted at all. To the extent that these two cases are part of a larger debate that includes the propriety of payments for *final* exclusion, review at this time would be premature. The latter issues have not yet been examined at the appellate level, and this Court should consider those courts' perspectives if it ultimately reviews the issue. "The more important an issue is, the more the Court would benefit by allowing the issue to percolate so it can avail itself of the wisdom of other courts before settling a momentous matter." Robert L. Stern, Eugene Gressman, et al., *Supreme Court Practice*, at 457 (8th Ed. 2002).

Forgoing review at this time would also allow for scholarly debate on the issue. Although several articles have examined the question of the proper analysis of exclusion payments in the pharmaceutical industry, *see* Pet. at 28-29, none has addressed the very recent split between the Sixth and Eleventh Circuits. Professor Hovenkamp's extensive analysis of these issues was

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10. Another case cited by Andrx is *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003), but the court there expressly noted that the case did *not* involve exclusion payments. *Id.* at *6. Although the court mused in dicta about the wisdom of a *per se* ban on such payments, it noted that "in fact there is a difference between the reverse payment case and other forms of settlement. In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market. In this case, in contrast, the settlement led to increased competition." *Id.*

published only in June 2003. Nor have scholars yet had any opportunity to analyze the FTC's extensive decision, issued only two weeks ago. This Court is entitled to the benefit of a full scholarly debate before addressing these issues.

Also worth noting in the context of maximizing the number of perspectives before the Court is the fact that the only defendant in this case is the generic company, Andrx. The owner of the relevant patent, HMR, has settled and is no longer a party to this litigation. Yet patentees obviously have an enormous stake in the issues. By contrast, the other currently pending cases include as active litigants not only the generic company but also the brand company that made the exclusion payment.

III. THE PETITION SHOULD BE DENIED BECAUSE THE SIXTH CIRCUIT RULING WAS ON AN INTERLOCUTORY APPEAL.

This Court has long recognized that interlocutory decisions such as that at issue here are generally inappropriate candidates for certiorari. "This Court should not issue a writ of certiorari to review a decree of the Circuit Court of Appeals on appeal from an interlocutory order, unless it is necessary to prevent extraordinary inconvenience and embarrassment in the conduct of the cause." *American Construction Co. v. Jacksonville, T. & K. W. Railway Co.*, 148 U.S. 372, 384 (1893); *see also Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916) ("Except in extraordinary cases, the writ is not issued until final decree"); *Brotherhood of Locomotive Firemen v. Bangor & Aroostock R. Co.*, 389 U.S. 327, 328 (1967) (denying certiorari "[b]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court"); *Virginia Military Institute v. United States*, 508 U.S. 946 (1993) (Scalia, J., concurring in the denial of certiorari noting that the Court will "generally await final judgment in a lower court before exercising our certiorari jurisdiction"). Andrx does not and cannot point to any "extraordinary inconvenience or

embarrassment" justifying any departure from this Court's reluctance to review interlocutory decisions.

The specific posture of this case graphically demonstrates the wisdom of that reluctance in two ways. First, Andrx's own argument demonstrates the inappropriateness of the interlocutory review that it seeks. Andrx contends that, in order to determine whether the Agreement is unlawful, a court must first determine whether the Agreement had an actual anticompetitive effect. *See* Pet. at 22-23. By this, Andrx means that a court must first determine whether, absent the Agreement, Andrx in fact would have entered the market earlier. *Id.* at 23.

The district court, here, however, has already held that there is a disputed issue of material fact – to be resolved at the trial set for April 12, 2004 – as to whether Andrx would have entered earlier absent the exclusion payments. In denying summary judgment to Andrx on this issue, the court explicitly ruled that there is substantial evidence in this record from which a jury could conclude that Andrx in fact would have come to market earlier. *In re Cardizem,* Order No. 80, at 49-50. Therefore, the very rule that Andrx urges this Court to adopt – that the Agreement is not unlawful unless Andrx would in fact have entered – has embedded in it a factual dispute that has not yet been resolved. Review by this Court of the interlocutory decision is accordingly premature. The existence of an unresolved fact central to a party's analysis counsels strongly in favor of the denial of certiorari.

Second, interlocutory review is also inappropriate here because this case, if allowed to proceed to final judgment, may be resolved on grounds that moot the entire question of the proper mode of analysis. Causation is a central issue remaining to be decided in this case. If Plaintiffs fail to prove at trial that Andrx would have entered earlier absent the Agreement, then Andrx caused Plaintiffs no injury regardless of whether Andrx violated the law. The issue raised by Andrx in its Petition would be moot.

Moreover, numerous decisions of significance have been entered, and will be made before, during, and after trial, by the district court before final judgment. Other decisions in these cases may ultimately merit review by this Court. Thus, granting certiorari in this case now might result in piecemeal review. Much efficiency would be gained at little cost by considering review of any relevant issues together and only after a final judgment is rendered.

IV. THE PETITION SHOULD BE DENIED BECAUSE THE TYPE OF AGREEMENT AT ISSUE IS PECULIAR TO THE PHARMACEUTICAL INDUSTRY AND, EVEN WITHIN THAT INDUSTRY, IS NOT LIKELY TO RECUR.

A. *The Type of Agreement at Issue Here Is Peculiar to the Pharmaceutical Industry.*

Contrary to Andrx's contention (Pet. at 25), the type of exclusion payment at issue in this case is peculiar to the pharmaceutical industry. Such payments are essentially unheard of in any other industry. This is so because it is the pharmaceutical industry's peculiar regulatory scheme under the Hatch-Waxman Act – in particular the 180-day exclusivity period for the first ANDA filer – that provides the necessary structure for these exclusion payments. *See* Hovenkamp, 87 Minn. L. Rev. at 1757.

The first generic manufacturer that files an ANDA with a Paragraph IV Certification is entitled to a 180-day period of exclusivity before the FDA can approve any other manufacturer's ANDA for the same product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Under the law as it existed at the time of the events giving rise to this and similar cases, the 180-day period did not begin to run until (1) a court found the generic product not to infringe the patent; or (2) the first-filer began commercial marketing of the product, whichever is earlier. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I-II) (1998). The patent holder's payment to

the first-filer to delay commercial marketing could therefore prevent *all* generic manufacturers from entering the market until a court decision concerning infringement.

As Professor Hovenkamp has noted, it is this unique regulatory scheme that resulted in the rash of pharmaceutical cases involving exclusion payments:

> Exclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments. Undoubtedly, what has increased their attraction under that statute is the fact – *unique to pharmaceutical patents* – that a properly defined settlement-plus-exit-payment keeps not only the immediate infringement defendant out of the market for a time, but also [through the 180 day exclusivity period] keeps other generic firms from entering as well.

Hovenkamp, 87 Minn. L. Rev. at 1757 (citations omitted) (emphasis added).

These exclusion payment agreements do not exist in other industries because, without such unique regulatory barriers, a payment to exclude one potential competitor could not result in the exclusion of all other potential competitors. A patent holder who made an exclusion payment to one competitor would be immediately confronted with the need to make similar payments to all other potential competitors. Without a unique entry barrier such as the Hatch-Waxman 180-day exclusivity, making a payment to one competitor is simply not worthwhile.[11]

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11. Andrx's suggestion that the Sixth Circuit's ruling has caused a decline in pharmaceutical innovation (Pet. at 26) – *i.e.*, the development of new drugs – is preposterous. The Pink Sheet article to which Andrx cites connects the decline in IND filings not to any court ruling, but to an overall decline in R&D productivity. *IND Filings Hit Seven-Year Low: Where is R&D Productivity*, Prescription Pharma. & Biotechnology ("The Pink Sheet") 8 (Nov. 10, 2003). Since the late 1980's, real

(Cont'd)

B. ***The Types Of Agreements At Issue Here Are Unlikely To Recur Because Recent Significant Legislative Changes To The Hatch-Waxman Scheme And Aggressive Enforcement Actions By The FTC Have Virtually Eliminated The Incentive For Exclusion Payments.***

Not only are exclusion payments unheard of in other industries, they may also be a thing of the past in the pharmaceutical industry. As noted, the major incentive for exclusion payments is the bottleneck that such payments create under the 180-day exclusivity provision of the Hatch-Waxman Act. Recent legislative changes to the Hatch-Waxman scheme and aggressive FTC enforcement have virtually eliminated any incentives to continue to enter into such payment agreements. Without such incentives, these agreements will likely disappear from the landscape regardless of whether the Court grants review of the Sixth Circuit's decision.

As to legislative changes, on December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. No.

(Cont'd)
innovation in the pharmaceutical industry has been on the decline, with the industry focused more on bringing to market "me-too drugs" (newer versions of older profitable drugs) than new drugs that are truly innovative. *See* National Institute for Health Care Management, Changing Patterns of Pharmaceutical Innovation, at 2 (2002) (of the 1,035 drugs approved by the FDA from 1989 to 2000, only 361, or 35%, contained new active ingredients) (available at http://www.nihcm.org/innovations.pdf). At this same time, pharmaceutical manufacturers' spending on R&D has increased. As the brand companies' trade association, Pharmaceutical and Research Manufacturers of America ("PhRMA"), recently reported: "[I]n 2002, both U.S.-owned and foreign-owned PhRMA member companies invested an estimated $32 billion in R&D. This amount represents a 7.7 percent increase over expenditures in 2001 and is more than triple the investment in 1990." Pharmaceutical Industry Profile, 2003, at 10, PhRMA (available at http://www.phrma.org/publications/publications/profile02/2003%20CHAPTER%202.pdf.).

108-173. This legislation strips the first ANDA filer of its 180-day exclusivity period if it fails to exercise its right to come to market in a timely fashion. P.L. No. 108-173, § 1102. Failure to come to market within 75 days of a qualifying court judgment *or settlement* will cause the total forfeiture of the generic company's 180-day exclusivity period. The amendment thereby eliminates the patent holder's ability to use an exclusion payment to the first ANDA filer to block entry of all other generic companies. The specific purpose of such a provision is to make exclusion payments ineffectual. *See* Prepared Statement of The Federal Trade Commission, Before the Committee on Judiciary, United States Senate, Washington, D.C. (Statement of Chairman Muris, August 1, 2003) (available at http://www.ftc.gov/os/2003/08/030801pharmtest.htm).

This legislative corrective has been coupled with aggressive FTC challenges to exclusion payment agreements. In connection with settling a challenge to such an agreement, the Commissioners announced on March 16, 2000 that: "[p]harmaceutical firms should now be on notice, ... that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm." *Abbott Labs. and Geneva Pharms.*, Docket No. C-3945 (2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary) ("FTC Commissioners' Statement") (available at *http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm*). The FTC Commissioners made clear that "in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits." *Id.* Indeed, since the FTC began its study of these agreements, not a single similar exclusion payment agreement has been entered into by any pharmaceutical manufacturer. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at viii (July 2002), *available at http:/*

/www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The continuously looming threat of a disgorgement remedy has likely put an end to the use of exclusion payments in the pharmaceutical industry. There is therefore little reason for the Court to reach out and review the Sixth Circuit decision.

CONCLUSION

In spite of the absence of full appellate and scholarly development of the relevant issues, Andrx has sought interlocutory review of a unique type of agreement that is highly likely to disappear from the pharmaceutical industry landscape. For the reasons stated above, Andrx's Petition to review the Sixth Circuit's straightforward application of settled law should be denied.

Respectfully submitted,

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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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David A. Balto & Michael Gallagher, *Recent Developments in Patent Settlement Litigation*, 1 Antitrust Rep. 39 (Fall 2003) 7, 8

Robert L. Stern *et al.*, Supreme Court Practice (8th ed. 2002) 5

Respondents (Plaintiffs) concede a circuit split. Opp. 17-18. The Eleventh Circuit rejected the Sixth Circuit's characterization of a patent settlement as illegal *per se* under the antitrust laws and declared intellectual property settlements legal, provided that they restrain competition no more than a court might. Pet. 12.

Only three months ago, Plaintiffs (who are also plaintiffs in the Eleventh Circuit) viewed the need to resolve this split as one of "exceptional" and "vital public importance." Appellees' Pet. for Reh'g at i, 2, *Valley Drug Co. v. Abbott Labs.* (11th Cir. 2003) (No. 02-12091-J). They warned that the Eleventh Circuit's rule of reason analysis would "halt . . . imminent competition" against "brand-name drugs with annual sales of more than $20 billion" and "legitimize the use of similar" agreements. *Id.* at 2. Their new position that the split is unimportant lacks credibility.

Plaintiffs' position now, that the *Sixth Circuit* applied a rule of reason analysis to the Stipulation's effects and benefits, is contradicted by the Sixth Circuit's express holding that any analysis of competitive effects or benefits was "irrelevant." Pet. App. 20a. It is further refuted by the Eleventh Circuit, Federal Trade Commission (FTC), each of the five *amici* here, and every academic, all of whom have read the decision as a *per se* ruling (with some supporting *per se* treatment and others opposing it). See, *infra*, pp. 7-9.

Plaintiffs' arguments for delay are equally meritless. This Court created the *per se* category of antitrust analysis. Because of its extraordinary force when imposed, this Court has frequently reached out to clarify its applicability to new types of agreements or circumstances. If anything, review now is more timely given the Sixth Circuit's *per se* condemnation on summary judgment. The Sixth Circuit's *per se* characterization is not only dispositive of the legality issue in this case; the circuit split is having a real effect on intellectual property settlements and licenses nationwide. As explained in the *amicus* briefs of two major intellectual property bar associations with over 15,000 members, lawyers

throughout the country have no choice but to advise their clients that, in every instance where Sixth Circuit law might apply, the *per se* ban affects "all patent settlements and license agreements in all industries." See, *infra*, p. 3. This Court's review is urgently needed.

I. The Federal Trade Commission's Recent Decision Demonstrates the Need for This Court's Review Now

This Court relies on the FTC for its expert views of the antitrust laws. *See FTC v. Cement Inst.*, 333 U.S. 683, 720 (1948). Although Plaintiffs invoke an FTC decision rendered after Andrx petitioned for *certiorari* (Opp. 13-15), they do not advise that the FTC explicitly *rejected* the Sixth Circuit's *per se* approach: In an extraordinary statement, the FTC held: "**We . . . do not believe the [Sixth Circuit's] opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach.**" *In re Schering-Plough Corp.*, No. 9297, Comm'n Op. at 13 & n.26 (FTC Dec. 18, 2003) (available at www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf) ("*Schering*") (citing *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999); *Nat'l Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 85 (1984)) (emphasis added). Addressing the circuit split, the FTC emphasized that antitrust challenges to patent settlements raise "important policy issues at the intersection of patent law and antitrust law." *Schering* at 1. Contrary to Plaintiffs' claim, the FTC recognized that the issue will recur and that its decision "would have an impact not only on this particular case but also on other antitrust cases before the Commission and the courts that involve the legality of patent settlements." *Id.* at 1, 30.

II. The Circuit Split Is Having Nationwide Effects

Plaintiffs wrongly assert that the direct conflict in the circuits is unimportant because it "only" concerns two circuits. Opp. 17. Plaintiffs ignore the Sixth Circuit's "conflict with the Federal Circuit's case law," Amicus Br. of American Intellectual Property Law Ass'n ("AIPLA Amicus Br.") at 2, 11, the multidistrict nature of the litigation

affected by the conflict (Pet. 18-19), and, most significantly, the fact that "[a]ny nationwide company that does business within the Sixth Circuit can be sued there and . . . made subject to its rule." Amicus Br. of Washington Legal Foundation ("WLF Amicus Br.") at 15.

The antitrust laws provide ample opportunities to choose a forum, and an explicit conflict between circuits on the critical question of whether a practice is *per se* illegal or subject to the rule of reason is an open invitation to parties to select a forum on that basis. Under the antitrust laws' nationwide jurisdiction provision, a plaintiff may sue "in any district wherein [the defendant] may be found or transacts business." 15 U.S.C. § 22. Thus, if the conflict is not resolved by this Court, plaintiffs seeking damages from the many corporations that do business throughout the country will flock to the district courts of the Sixth Circuit. By contrast, parties facing an adverse FTC determination (such as *Schering*) will likely seek review in the Eleventh Circuit. *See* 15 U.S.C. § 45(c) (jurisdiction to review FTC order lies in any circuit where challenged practice was used or corporation carries on business).

Plaintiffs' contention that the conflict in the circuits will affect only the pharmaceutical industry is also unpersuasive. Opp. 23-24. The situation would be untenable even were Plaintiffs correct, but they are plainly not. Nothing in the logic of the Sixth Circuit's decision is so limited, as explained in the amicus briefs of the two pre-eminent intellectual property bar associations. That is why the American Intellectual Property Lawyers' Association has represented to the Court that its members now routinely advise clients (pharmaceutical or not) that "the Sixth Circuit's *per se* rule extends to **all** patent settlements and license agreements in **all** industries." *See* AIPLA Amicus Br. at 1 (emphasis added); *id.* at 7-8. For AIPLA's 15,000 members (AIPLA Motion at 1), the ruling "introduces enormous uncertainty into routine agreements." AIPLA Amicus Br. at 6. They predict "[a] corresponding reduction

in the number of patent settlements and licenses" with significant economic repercussions. *Id.* at 9.

Their concern is driven by the absence of any logical distinction between the cash payment condemned by the Sixth Circuit and other forms of consideration, such as routine waivers of accrued damages or future licenses. *See* Pet. 16-18. Despite Plaintiffs' *ipse dixit* that such consideration may be lawful (Opp. 9 n.4), the Sixth Circuit did not limit its holding to cash payments or interim settlements. Its rationale necessarily implies that **any** consideration will unlawfully "bolster" a patent's power. *See* Amicus Br. of N.Y. Intellectual Property Law Ass'n ("NYIPLA Amicus Br.") at 13 ("Sixth Circuit provided no rationale for distinguishing between" the settlements it addressed and other agreements). Indeed, even Plaintiffs have argued that licenses and settlements are anticompetitive. Brief of Individual Sherman Act Plaintiffs-Appellees at 36-38 n.19, *In re Cardizem CD Antitrust Litig.*, (6th Cir. 2003) (No. 00-2483) ("Pl. 6th Cir. Br."). Most significantly, lawyers read the Sixth Circuit decision as indicating that "any type of consideration flowing from a patentee to a potential infringer as part of the overall agreement would render the agreement *per se* illegal." AIPLA Amicus Br. at 1. These practitioners face "confusion" "as they struggle to counsel their clients" regarding the legality of otherwise standard patent settlements and licenses "while the conflict remains unresolved." NYIPLA Amicus Br. at 5; *id.* at 8-15.

III. There Is No Reason to Prolong the Circuit Split Pending Trials of Collateral Issues

That the Sixth Circuit found *per se* illegality on summary judgment (*see* Opp. 21-23) is surely not a reason to ignore the circuit split. *See, e.g., EEOC v. Waffle House, Inc.*, 534 U.S. 279, 284-85 (2002) (reversing pretrial interlocutory decision concerning ability to recover non-injunctive relief).

The Sixth Circuit found Andrx's conduct illegal based on a determination that *per se* condemnation rather than rule

of reason review governs the Stipulation. Such a fundamental and broad ruling on antitrust liability is one that this Court has historically considered on an interlocutory basis. *See, e.g., Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 336-37 (1982) (granting review of order certified under 28 U.S.C. § 1292(b) to determine whether *per se* doctrine or rule of reason should govern); *Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 643-44 (1980) (same). Further proceedings below will not amplify the record on the legality of the Stipulation because the lower courts cut off any inquiry through discovery and trial into the actual benefits of the Stipulation. *See* Pet. App. 50a. The intellectual property bar and pharmaceutical manufacturers need immediate guidance from this Court regarding the proper antitrust analysis to be employed. *See, e.g.*, NYIPLA Amicus Br. at 2-3.

Review is appropriate because the question presented is "an important and clear-cut issue of law," on which the circuits are cleanly divided, that is "fundamental to the further conduct" of several trials that this multidistrict litigation will produce. *See* Robert L. Stern *et al.*, Supreme Court Practice § 4.18 at 259 (8th ed. 2002).[1] Indeed, where, as here, an interlocutory appeal is certified under 28 U.S.C. § 1292(b), the nonfinal nature of the order should not delay review, as the certification itself "incorporates some of the considerations relevant to the Court in deciding whether to review any nonfinal judgment." *Id.* § 4.19 at 261; *see, e.g.*, *Beneficial Nat'l Bank v. Anderson*, ___ U.S. ___, 123 S. Ct. 2058, 2061 (2003); *Breuer v. Jim's Concrete of Brevard, Inc.*, 538 U.S. 691, ___, 123 S. Ct. 1882, 1884 (2003).

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[1] Contrary to Plaintiffs' implication (Opp. 22), only one case in this multidistrict litigation is tentatively scheduled for an April trial in Michigan. Another was just referred for remand to a district court in Florida (in the Eleventh Circuit) where it should be tried.

IV. The Legislation Plaintiffs Cite Is Wholly Irrelevant

Plaintiffs wrongly assert that the settlements at issue are a "thing of the past" (Opp. 25), claiming that recent legislation removes the incentive for entering into such agreements by providing for a "total forfeiture of the generic company's 180-day exclusivity period" within 75 days of entry of a settlement (Opp. 26).[2] In fact, the forfeiture provision Plaintiffs cite is wholly inapposite to the settlements at issue, will not deter future settlements (*see* Amicus Br. of Pharm. Research Mfrs. of America at 3 n.2), and is irrelevant to the antitrust issues here. Congress has not addressed and will not address the Sixth Circuit's *per se* ban; that is the province of this Court. Pet. 25; *see also State Oil Co. v. Khan*, 522 U.S. 3, 21 (1997) (Court does not leave Sherman Act changes to Congress because courts are expected "to give shape to the statute's broad mandate by drawing on common-law tradition").

The legislation Plaintiffs cite is triggered only if "**a court signs a settlement** order or consent decree **that enters a final judgment that includes a finding that the patent is invalid or not infringed**." Pub. L. No. 108-173 § 1102(a)(2) (emphasis added). Thus, typical settlements, entered into with no finding of wrongdoing, without court involvement, or on an interim basis, trigger no forfeiture. The FTC understood that these legislatives changes (which it

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[2] Since Plaintiffs do not seek damages based on any claim that Andrx delayed the sale of its reformulated product or would have relinquished any exclusivity right, *see In re Cardizem CD Antitrust Litig.*, 99 MDL 1278, Order No. 80, slip op. at 50 n.11 (E.D. Mich. Nov. 13, 2003), Plaintiffs' references to those issues (Opp. 4, 10 n.5) are red herrings. Similarly, the alleged "bottleneck" cited by Plaintiffs (*id.*) was a product of a subsequent change in law, not the Stipulation, and is not at issue here. *See* 66 Fed. Reg. 18636, 18637 (2001) (during the relevant time "the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's suit in order to be entitled to this exclusivity").

commented on (*see* Opp. 26)) would not resolve the critical antitrust issues presented here. It emphasized the "increase in pioneer/generic patent litigation and . . . litigation settlements" that could be affected by its ruling. *Schering* at 1, 30. Another provision, facilitating FTC review of certain patent agreements, renders it "of critical importance to the patent community that the FTC . . . obtain the authoritative guidance of this Court" regarding how to evaluate such agreements. NYIPLA Amicus Br. at 18; *id.* at 8.

V. The Issue Is Ripe For Review

In addition to the FTC's expert views expressed in *Schering*, this Court has at its disposal the considered views of the scholars who have fully addressed whether intellectual property settlements should be subject to *per se* liability, with well over a dozen articles published over the past five years. *See, e.g.*, Pet. 28-29 & n.3 (citing articles); Opp. 9 n.4, 12 (same). As one of the commentators relied on by Plaintiffs recently stated in analyzing the split between the Sixth and Eleventh Circuits, "[p]robably few areas of antitrust law are the subject of as much antitrust litigation or academic commentary as the settlement of patent litigation in the pharmaceutical industry." David A. Balto & Michael Gallagher, *Recent Developments in Patent Settlement Litigation*, 1 Antitrust Rep. 39, 39 (Fall 2003) ("Balto"). "Percolation" is unlikely to produce new insights, and a delay in resolving the conflict will prejudice the many businesses that need certainty and uniformity in this area of the law.

VI. The Circuit Split Concerns Fundamental Principles

A. The Appropriate Scope of Antitrust Review

Recognizing that *per se* treatment in the context presented here is indefensible, Plaintiffs suggest that the Sixth Circuit's use of the *per se* label was mere semantics and that that court actually conducted a rule of reason review weighing procompetitive justifications, the "regulatory context" and the patent's "exclusionary power." *See* Opp. 1,

6, 11-12, 14; *id.* 9-10 (citing inapposite antitrust injury discussion).

Plaintiffs' strained and unpersuasive reading of the Sixth Circuit's decision is inconsistent with that of every objective reader, including the former FTC official relied on by Plaintiffs (Opp. 11 n.5), who stated that "by applying the per se rule, **the Sixth Circuit cut off any inquiry into the procompetitive benefits of the settlement, and, thus, did not address defendants' arguments on that topic**." Balto, 1 Antitrust Rep. at 44 (emphasis added); *see also* AIPLA Amicus Br. at 3 (Sixth Circuit "found the agreement *per se* illegal without considering the procompetitve justification").

In an antitrust case, the "essential inquiry" is "whether or not the challenged restraint enhances competition." *Cal. Dental*, 526 U.S. at 780. The Sixth Circuit used the *per se* characterization to jettison that entire inquiry as "irrelevant." Pet. App. 20a; *see* WLF Amicus Br. 6-9 (detailing distinction between *per se* and rule of reason analysis). The Eleventh Circuit, on the other hand, rejected both *per se* and rule of reason condemnation, holding that a patent settlement is lawful if the restraint imposed on the alleged infringer is no broader than a restraint the patentee could plausibly obtain from a court. Pet. App. 147a & n.27. The circuits thus reached opposite conclusions regarding a question that has historically warranted this Court's review, the appropriate contours of this Court's *per se* rule. *See, e.g., Cal. Dental*, 526 U.S. at 764-65; *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998); *State Oil*, 522 U.S. at 9.

Far from conducting a rule of reason analysis, the Sixth Circuit bluntly held that Andrx's "claims that the [Stipulation] lacked anticompetitive effects and had procompetitive benefits are **simply irrelevant**." Pet. App. 20a (emphasis added). In applying the *per se* rule, the court "presume[d]" the Stipulation anticompetitive **without** "evaluat[ing] the **actual** anticompetitive effects or procompetitive justifications." Pet. App. 20a (emphasis added).

Thus, unlike *Schering*, where the FTC applied a rule of reason analysis examining the actual competitive effects after a full trial, the courts below condemned the Stipulation here before discovery, and before Andrx could engage experts in the case, let alone develop and proffer evidence of the Stipulation's actual effects. The lower courts adopted Plaintiffs' position – not even defended here – that "inquiry into the purpose or benefits" of the Stipulation is neither "warranted [nor] permitted" and "[a]ll attempts . . . to justify such an agreement as 'procompetitive' must be rejected." Pl. 6th Cir. Br. at 15;[3] *see* Pet. App. 19a-21a, 81a. As the FTC concluded, such a summary rejection of competitive effects and benefits is not a rule of reason analysis and creates a direct conflict in the circuits. *Schering* at 7, 12-13, 15, 29; *id.* at 13 n.26, 29 (rejecting *Cardizem*; requiring "more extensive analysis of competitive effects").

B. The Significance of Patent Ownership

Even Plaintiffs concede that the Sixth and Eleventh Circuits split over a "fundamental" issue that may be outcome determinative: the "scope of the exclusionary right actually granted by Congress in the patent law." *See* Opp. 17-18.[4] Plaintiffs seek to downplay that "fundamental" split by asserting that the circuits merely addressed interim settlements implicating "pretrial" patent exclusionary effects. Opp. 17-19. But as the *amici* understand, all settlements (final or interim) concerning unadjudicated patent rights implicate the issue of whether the exclusionary right flows from the patent grant or the judgment enforcing it.

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[3] Plaintiffs' present reliance on Professor Hovenkamp (Opp. 12) contradicts their prior position that his "general analysis of patent settlements is subject to serious criticism." Pl. 6th Cir. Br. at 36.

[4] Plaintiffs' reliance on cases addressing whether the antitrust laws must accommodate state law restrictions on competition (Opp. 16) is misplaced in light of their concession that antitrust law must accommodate federal patent law (Opp. 7). *See* Pet. 23.

The split acknowledged by Plaintiffs is important. Before the Sixth Circuit's decision, the intellectual property bar was confident that the patent grant itself entitled the patente owner to freedom from infringing competition. *See* AIPLA Amicus Br. 9-11. This position was grounded in the statutory "**right to exclude** others," 35 U.S.C. § 154(a)(1), which "provides the basis for affording the patentee . . . an award of damages" for infringement that "has already occurred" prior to a judicial adjudication, *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 522 (1972), as well as a preadjudication presumption that any infringement will lead to irreparable harm, *Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 973, 976 (Fed. Cir. 1996). Plaintiffs view the Sixth Circuit decision as rejecting that position and holding that "[t]he reward actually granted by Congress to patent holders for their innovation is only *some probability* . . . of being able to exclude competitors." Opp. 12, 17-18. This view, which Plaintiffs contend was rejected by the Eleventh Circuit (Opp. 17-18), is of great importance to intellectual property owners who invested in property that they believe **is** theirs, not "probably" theirs. Even as mischaracterized by Plaintiffs, the circuit split cannot be viewed as narrow or trivial.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

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January 7, 2004

(8)

No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

SUPPLEMENTAL BRIEF FOR THE PETITIONER

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The Solicitor General agrees with Petitioner that it is "erroneous" (U.S. Br. 12) to apply the *per se* rule to patent settlements in which the patentee pays the alleged infringer to exit the market and that whether to ban such settlements is an "important" issue (*see id.* 7). Yet he recommends against certiorari based on his supposedly "better reading" of the Sixth Circuit opinion that, even if right, would only slightly limit the glaring conflict with the Eleventh Circuit decision (*id.* 12-13). No fair reading of the Sixth Circuit opinion supports his view, which is the Solicitor General's alone. The Federal Trade Commission (FTC), each of the five supporting amici, every major intellectual property association in the Nation, every court to have addressed it (including Judge Posner), each of the many commentators to speak to it, and Respondents themselves all acknowledge the circuit split. *Infra* pp. 3-4. The Solicitor General's singular and strained supposition can be explained only by the government's stake in this matter, which, as this Court has recognized, deprives the Solicitor General's views of persuasive weight. *Infra* pp. 7-8. The Court should grant the Petition and consider summarily reversing the Sixth Circuit's "erroneous" application of the *per se* rule. *Infra* p. 10.

1. Setting aside the Solicitor General's bizarre reading of the Sixth Circuit decision (addressed *infra* pp. 4-7), his brief plainly supports the urgent need for the Court to grant the Petition. The Solicitor General agrees that exit or "reverse" payments are not *per se* unlawful (U.S. Br. 7-11); states that a contrary conclusion would violate "well-established principle[s]" (*id.* 7); and agrees that the Sixth Circuit decision is "erroneous" to the extent it "deem[s] illegal per se every settlement agreement that includes a reverse payment" (*id.* 12). He also agrees that the Eleventh Circuit "rejected" the view that such settlements are *per se* illegal. *Id.* 11.

2. Nor does the Solicitor General dispute that, no matter how the Sixth Circuit opinion ***should*** be read, there is surely a "perceived conflict" among the circuits, which is sufficient

to grant the Petition, *Darby v. Cisneros*, 509 U.S. 137, 142-43 (1993), given the obvious "tension" in the circuits, *Baral v. United States*, 528 U.S. 431, 434 (2000).

The Solicitor General nowhere questions AIPLA's position that its 15,000 members reasonably perceive *Cardizem* as "call[ing] into question the legality of commonly accepted provisions in patent settlement and license agreements" thus endangering "**all** patent settlements and license agreements in **all** industries" nationwide. *See* AIPLA Br. 1.[1] Nor can he, given the uniformity of disinterested views acknowledging the profound importance of the split – views that continue to be expressed. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1067 (2004) ("[m]any, maybe most, patent settlements include reverse payments. . . . If reverse payments are to be condemned without more, we may have no patent settlements at all").

Indeed, Judge Kenneth W. Starr, in a recent amicus brief penned for the generic pharmaceutical industry's challenge to the FTC's more forgiving *Schering* standard, warns of "staggering consequences" from the new "anti-settlement approach" (endorsed in *Cardizem*) that "expose[s] to potential antitrust liability not just every Hatch-Waxman settlement involving money, but virtually ***every*** settlement in patent, antitrust, or intellectual property cases." Amicus Br. of Generic Pharm. Ass'n at 21, *Schering-Plough v. FTC* (11th Cir. Jun. 8, 2004) (04-10688-AA) (original emphasis). The Solicitor General takes no issue with the reality that both innovators and patent challengers are being chilled given the "implicit exchange of money during the settlement of every patent lawsuit." *Id.* 4, 7, 21; *see* Pet. Rep. 4 (consideration exchanged in licenses and damage releases). Nor does he dispute that nationwide jurisdiction and multidistrict proceedings magnify this effect. Pet. 18-19; Pet. Rep. 3.

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[1] All emphases in this brief are added unless otherwise indicated.

3. The Solicitor General is alone in refusing to acknowledge the circuit split. The Eleventh Circuit politely "recognize[d] that the Sixth Circuit appeared to take the opposite view" but clearly concluded "we respectfully disagree." Pet. App. 145a, 146a n.26. The FTC also could not have been clearer: while "[*Cardizem*] found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry," "[t]he even more recent decision[] in *Valley Drug* . . . **expressly considered contrary authority and declined to apply the *per se* label**." *In re Schering-Plough Corp.*, No. 9297, Comm'n Op. 12-13 (FTC Dec. 18, 2003), appeal docketed *sub nom. Schering-Plough Corp. v. FTC*, No. 04-10688-AA (11th Cir. Feb. 13, 2004) ("*Schering*"); *see also FTC Official Says Some Effects of Recent Patent Law Reform Could Be Anticompetitive*, 2 Pharm. L. & Indust. Rep. 118 (Jan. 30, 2004) ("'This is one issue the Supreme Court's going to have the last word on,' [**FTC official** Michael S.] Wroblewski said, **noting that there is a split in the circuits** . . . with the Sixth Circuit applying a *per se* approach . . . and the Eleventh Circuit applying a rule of reason") (expressing personal views at conference); Michael B. Kades, "How FTC Policy & Practice Affects Decision Making," *Conference on Latest Thinking on Attacking/Defending Patents in the U.S. Pharmaceutical Market* (October 1, 2003) (**FTC official states** his view that *Cardizem* and *Valley Drug* "**Courts Have Split** Over" whether exit payments are *per se* illegal).

AIPLA and the other supporting amici also recognize the split, *see* AIPLA Br. 1-2 ("The Sixth Circuit's *per se* holding **conflicts directly** with [*Valley Drug* and *Schering*]" and Federal Circuit misuse case law), as does the American Bar Association, *see Antitrust & Intellectual Property*, vol. 5, no. 1 at 4 (Spring 2004) (ABA's Antitrust Section Intellectual Property Committee newsletter: *Valley Drug* "decision **sets up a direct conflict** with the Sixth Circuit"), and the New

York intellectual property bar. NYIPLA Br. 4-5 ("**stark conflict**" between *Cardizem* and *Valley Drug*).

Even the scholars cited by the Solicitor General (U.S. Br. 10 n.4, 14, 16) contradict his position and recognize the split. *See* Herbert Hovenkamp, Mark D. Janis, Mark A. Lemley, *Balancing Ease & Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712 n.3 (2004) (describing Sixth Circuit opinion as "finding exclusion payments in pharmaceutical patent settlements illegal per se," in direct conflict with Eleventh Circuit's "rejecti[on of] per se illegality"). These authorities acknowledge that "the legality of reverse payments **remains very much a live, and hotly contested issue**" and that "two federal courts of appeals have now offered **diametrically opposing views** of these settlements." Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments*, 71 Antitrust L.J. 1069, 1069-70 (2004).

Finally, Respondents here (Pet. 9), as well as the *Valley Drug* petitioners (*see* Petition at 1, *Valley Drug Co. v. Geneva Pharm., Inc.* (03-1175)) and counsel for respondents (*see* Robert A. Milne & Michael J. Gallagher, *Recent Activity on the Brand-Generic Patent Settlement Front*, 18 Antitrust 83, 83 (Spring 2004)) acknowledge the "important" split.

4. The Sixth Circuit's language does not support the Solicitor General's peculiar view. He asks this Court to ignore the "broad language in the Sixth Circuit's opinion" (U.S. Br. 12), explicitly condemning the Stipulation's restraint on Andrx's original product, because the Sixth Circuit *also* cites certain pages of the district court opinion and another district court opinion that reference, among other things, the Stipulation's supposed restraint of "non-infringing" products and conduct (*id.* 14-15). The government says the true holding of the Sixth Circuit decision is this stray hair on the tip of the tail, and not the dog. This analysis fails.

To begin, even if the Sixth Circuit's ruling had been limited in the way the Solicitor General imagines, it would

still manifest a circuit split on a significant issue. As the Eleventh Circuit recognized, every settlement agreement reaches products that have not yet been finally adjudged to be either infringing or non-infringing. The Solicitor General's suggestion that the Sixth Circuit's ruling is limited to agreements that "reach[] non-infringing products" (U.S. Br. 13) would therefore require conducting the very litigation that the settlement was designed to avoid – and hence the circuit split.

Moreover, whatever else they did, the district court and Sixth Circuit condemned what they saw as the core restraint involving Andrx's infringing original product, not (and certainly not only) any claimed inconsequential additional restraints. Respondents alleged that, but for the Stipulation, Andrx would have launched its **original** generic product in June 1998 upon FDA approval. Pet App. 10a-11a. The district court knew that those "complaints do **not** assert antitrust claims for damages based on the theories that the [Stipulation] caused Andrx to (1) delay the sale of its June 1999 FDA approved reformulated generic product, and (2) forego relinquishing its right to the 180-day exclusivity period." *In re Cardizem CD Antitrust Litig.*, 99 MDL 1278, Order No. 80, slip. op. 50 n.11 (E.D. Mich. Nov. 13, 2003). It therefore cannot be that the *per se* holding in this damages case pertained to a violation as to which no damage is alleged. *See* Pet. App. 31a-33a. As the district court held, "the Sixth Circuit . . . necessarily rejected Andrx's arguments that only competition proven to be non-infringing is worthy of protection under the antitrust laws." Order No. 80 at 29.

The Sixth Circuit clearly stated what it was affirming: "The district court concluded that the Agreement, specifically the fact that HMR paid Andrx $10 million per quarter not to enter the market with **its generic version** of Cardizem CD, was a naked, horizontal restraint of trade and, as such, *per se* illegal." Pet. App. 13a-14a. The "generic version" both courts referred to was Andrx's original, allegedly infringing product approved by the FDA in July 1998. Pet. App. 19a

n.14 (district court addressed original, not reformulated product); *see id.* 7a (HMR alleged that "generic version of Cardizem CD that Andrx proposed would infringe"), 9a ("Andrx did not bring its generic product to market" upon July 1998 FDA approval). In its antitrust injury discussion, the Sixth Circuit described its *per se* holding as limited to the allegedly infringing "FDA-approved" product (Pet. App. 31a-32a), not some non-infringing alternative. Indeed, in setting out the "dispositive" facts supporting its finding of *per se* illegality, it never once referred to any potentially or actually non-infringing product. Pet. App. 17a-18a. It understood that Respondents were merely claiming that "from July 1998 through June 1999, Andrx kept its generic product off the market," "even after it had obtained FDA approval" for its allegedly infringing product. *Id.*

Were the Sixth Circuit's decision "hardly novel" (U.S. Br. 14), the FTC would not have explicitly criticized it for failing to take "adequate account of Supreme Court decisions that mandate a more nuanced approach." *Schering* at 13 n.26. Judge Posner's criticisms of the Sixth Circuit, *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003), only make sense if Judge Posner understood, as everyone else has, that the Sixth Circuit condemned as *per se* illegal an agreement involving an allegedly **infringing** product. Indeed, the widespread outcry regarding the Circuit's failure to account for the patentee's right to exclude cannot be squared with a construction of *Cardizem* that limits it to admittedly non-infringing products. *See* Stephen A. Stack, Jr., *Afterword: Some Further Observations on the "Pharmaceutical Wars,"* 71 Antitrust L.J. 705, 713 (2003) ("These two cases represent a binary approach; the patent is given no exclusionary effect in *Cardizem* and full exclusionary effect in *Hytrin.*").

Most significantly, the Solicitor General's tortured reading is of no practical significance. No responsible counsel aware of the Sixth Circuit's opinion would advise a client subject to suit in that circuit to settle a patent case with

a "reverse payment." As the amici amply demonstrate, it is that chill that is so profoundly affecting agreements at the heart of the new economy. *See* Pet. Rep. 3-4.[2]

5. This is not the Solicitor General's first effort to dissuade this Court from acting in its historical role of preventing overuse of the blunt and powerful *per se* rule that this Court adumbrated (Pet. Rep. 1; NYIPLA Br. 3). Consider the significant *per se* decisions over the past two decades. The Solicitor General opposed review in *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999), yet the Court granted review and, disagreeing with the government, ruled that a full rule of reason analysis was appropriate. And in at least two other cases, the Solicitor General recommended against review, as it does here; yet in both cases the Court granted certiorari and reversed the lower court's expanded application of the *per se* rule. *See* Brief for U.S. & FTC as Amici Curiae, *NYNEX Corp. v. Discon, Inc.* 525 U.S. 128 (1998) (No. 96-1570); Petitioner's Supp. Brief & Response to Brief for U.S. as Amicus Curiae, *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284 (1985) (No. 83-1368). This Court also granted review in a fourth case to ensure immediate uniformity by limiting the application of the *per se* rule, even though the Solicitor General's amicus brief opposed review, arguing that the lower courts would in time get it right. *See* Brief for U.S. as Amicus Curiae, *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717 (1988) (Nos. 85-1910/2094).

Deference is even less appropriate where the Solicitor General is not a disinterested observer. The FTC is a litigant before the Eleventh Circuit in *Schering*, which may well be affected by a decision from this Court, and evidently is

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[2] The government's strained factual distinction between *Cardizem* and *Valley Drug* – that one challenged both infringement and validity while the other only validity (*see* U.S. Br. 11) – fares no better. In both cases, defendants denied that they infringed a valid patent. Pet. App. 6a-7a, 123a. The distinction is so immaterial that even Respondents concede that both cases present "**identical facts**." *See* Pet. 9.

seeking to preserve time on this Court's docket for its own litigation. As the Nation's leading antitrust enforcer, the government tends to discount the significance of over-enforcement, including the deterrent effect that the Sixth Circuit decision is having right now on pro-competitive settlements. While the government now acknowledges that so-called "reverse payment" settlements should not be unlawful *per se*, the FTC has "vigorously enforced" the law to discourage such settlements.[3] As the Solicitor General emphasizes, the FTC was Andrx's adversary in a challenge to the very settlement at issue here. U.S. Br. 4, 13.

6. The Solicitor General asserts that because the Sixth and Eleventh Circuits both addressed interim settlements, this Court's review "would not necessarily offer guidance" for "final patent infringement settlements." U.S. Br. 17-18. But resolving the circuit split on interim settlements is itself important. In any event, a settlement's interim nature is irrelevant to the issue presented in this case, *i.e.*, whether a *per se* rule applies.

The guidance to be offered here is that patent settlements involving exit payments should be analyzed under the rule of reason. That guidance would apply to both interim and final agreements because, for purposes of the *per se* rule's inapplicability, the patent's exclusionary effect is the same. Pet. Rep. 4. Tellingly, the FTC, in its own litigation, has made no effort to draw such a distinction. Brief of FTC, *Schering-Plough Corp. v. FTC* (11th Cir. 2004) (not drawing a single interim/final distinction).

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[3] Timothy J. Muris, Statement of FTC Before Senate Judiciary Comm., S. Hrg. 108–250 at 30 (June 17, 2003) (referencing FTC's "vigorous enforcement"); William M. Sage, *Protecting Competition & Consumers: A Conversation With Timothy J. Muris*, 22 Health Affairs 101, 106 (2003) (FTC Chairman discussing enforcement aimed at brands' "attempt[s] to bribe the generics to stay out of the market"); R. Hewitt Pate, *Antitrust & Intellectual Property*, Address to AIPLA (2003) 11-12) ("FTC, in particular, has been active in the area of patent settlements").

Nothing in the Solicitor General's critique of the *per se* rule in the "reverse payment" context suggests that his conclusion turns on the settlement's interim or final nature. *See* U.S. Br. 12. When the Solicitor General summarizes the Sixth Circuit decision, he never cites language discussing the interim nature of the settlement or limiting the holding to that context. *See, e.g.*, *id.* 6; *see also id.* 5. Indeed, his "interim" discussion contains not one quote from the Sixth Circuit, *id.* 15-18, let alone one distinguishing interim from final agreements. *See also* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments*, 87 Minn. L. Rev. 1789, 1800 (2003) (finding same antitrust concerns "[i]n either form" of settlement), *cited at* U.S. Br. 16. Nothing in the Sixth Circuit's analysis of *per se* liability turns on the interim character of the agreement.

The Solicitor General suggests various aspects of an interim settlement that might make it less pro-competitive than a comparable final settlement. *See* U.S. Br. 17. But these erroneous assertions bear only on whether interim and final settlements should be treated differently under the rule of reason, a question that would not be before this Court.

Consider the irony of the Solicitor General's suggestion that review "is unnecessary at this time" because interim settlements "appear to be rare." U.S. Br. 1, 16. One would expect interim settlements of intellectual property preliminary injunction motions to be commonplace given the prevalence of such motion practice, *see* L. Craig Metcalf, *Preliminary Injunctions & Their Availability*, 15 AIPLA Q.J. 104, 105-06 (1987), and, until the recent *per se* rulings, they were. *See* Pet. Rep. 3-4. The alleged infringer avoids such motion practice by agreeing to stay off the market in return for the patentee's promise to post a bond or pay a like amount to the alleged infringer *pendente lite*. *See* Pet. App. 145a. If the Sixth Circuit's decision is not reversed by this Court, such settlements will continue to be chilled.

7. The Solicitor General's unsupported view that recent legislation "**may**" reduce Hatch-Waxman settlements (U.S. Br. 18) is irrelevant. The Sixth Circuit explicitly invoked a "uniform" *per se* rule "applicable to all industries alike." Pet. App. 18a, 19a. Hatch-Waxman aside, the Sixth Circuit's decision eliminates all exit payments and chills settlements containing other forms of consideration flowing to alleged infringers in **all** industries. AIPLA Br. 1.

8. Given the views of the Respondents and the Solicitor General, we now wish to offer a suggestion for summary reversal. The Sixth Circuit's error is manifest, as the Solicitor General's analysis of the *per se* issue shows. Respondents are half-hearted – or less – in their defense of *per se* liability, and even claim (erroneously) that a rule of reason was applied. *See, e.g.*, Opp. 1, 6, 11-12, 14. The Solicitor General's lone view aside, there is widespread consensus that the Sixth Circuit's approach conflicts with that of the Eleventh Circuit. As the supporting amici demonstrate, as long as the Sixth Circuit decision remains law, it can only create mischief by discouraging potentially pro-competitive settlements. A reversal of the decision below, with instructions to apply the rule of reason, would eliminate that mischief, remove the conflict in the circuits, and correct an obvious error.

CONCLUSION

The petition for a writ of certiorari should be granted.

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No. 03-779

In the Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC., PETITIONER

v.

KROGER COMPANY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the court of appeals erred in holding that an interim agreement between the parties to patent infringement litigation constituted a per se violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's invitation to the Solicitor General to express the views of the United States. The position of the United States is that this Court's review is unnecessary at this time. The decision below may not conflict with any other court of appeals' decision, this case arises in a somewhat atypical factual setting, and statutory changes post-dating the events at issue here may affect the frequency with which similar questions will arise in the future.

STATEMENT

1. Respondents, Kroger Co. and other pharmaceutical purchasers, contend that an agreement among parties to a patent infringement suit violated the federal antitrust laws. The patent suit arose in the statutory context created by the Drug Price Competition and Patent Term Restoration Act of

1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the entry of lower-priced generic drugs while maintaining incentives to invest in new drug development.

Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved, another company seeking to market a generic version of the drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart. 21 U.S.C. 355(j). The FDA may approve the marketing of a generic drug prior to the expiration of a patent relating to the brand name drug if the applicant makes a "paragraph IV certification" that certifies that the patent in question is invalid or is not infringed by the generic product. 21 U.S.C. 355(j)(2)(A)(vii). If the patent holder files a patent infringement suit within 45 days after receiving notification of such a certification, the FDA's approval is automatically stayed for 30 months, unless the patent expires or is judicially determined to be invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). The first company to file an ANDA with a paragraph IV certification relating to a particular brand name drug is granted the exclusive right to market a generic version for 180 days after it begins commercial marketing or a court holds the patent invalid or not infringed. 21 U.S.C. 355 (j)(5)(B)(iv).[1]

2. Cardizem CD is a brand-name prescription drug which contains a controlled-release formulation of diltiazem hydrochloride. The formulation's dissolution profile—0%-45% of the total diltiazem to be released within 18 hours—is pro-

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[1] In 2003, Congress amended the Hatch-Waxman Act in various respects. See pp. 18-19, *infra*.

tected by U.S. Patent No. 5,470,584 (the '584 patent). Pet. App. 6a-7a. On September 22, 1995, petitioner, Andrx Pharmaceuticals, Inc., filed an ANDA with the FDA seeking approval to market a generic version of Cardizem CD. Petitioner thereafter filed a paragraph IV certification stating that its generic product did not infringe any of the patents listed with the FDA covering Cardizem CD. Because petitioner was the first to file an ANDA and paragraph IV certification with the FDA, it was eligible for the 180-day exclusivity period under 21 U.S.C. 355(j)(5)(B)(iv). Pet. App. 6a.

In January 1996, Carderm Capital, L.P., the owner of the '584 patent, and Hoechst Marion Roussel, Inc. (HMR), Carderm's licensee and the manufacturer of Cardizem CD, filed a patent infringement suit against petitioner, which triggered the 30-month stay of FDA approval under 21 U.S.C. 355(j)(5)(B)(iii). Pet. App. 7a. Petitioner counterclaimed against HMR, alleging antitrust violations and unfair competition. *Ibid.*

In September 1997, shortly after the FDA announced that it would approve petitioner's ANDA, effective upon termination of the automatic 30-month stay, petitioner and HMR entered into an agreement that settled petitioner's antitrust and unfair competition counterclaims and provided for interim arrangements relating to the patent infringement claims (the Agreement). The Agreement provided that (a) petitioner "would not market a bioequivalent or generic version of Cardizem CD in the United States" until it obtained "a favorable, final and unappealable determination" in the patent case or HMR licensed petitioner or a third party; (b) petitioner would continue to prosecute its ANDA and not relinquish its 180-day exclusivity rights; and (c) HMR would make quarterly payments to petitioner from the date that FDA approval of the ANDA became effective until entry of a final and unappealable judgment in the patent case (or

certain other events). Pet. App. 8a. HMR began making payments to petitioner under the Agreement in July 1998.

In September 1998, petitioner supplemented its ANDA to seek approval for a reformulated generic version of Cardizem CD that permitted not less than 65% of total diltiazem to be released within 18 hours. Pet. App. 40a-41a. The FDA approved the supplemented ANDA on June 9, 1999. *Id.* at 9a. HMR, apparently conceding that the reformulated product did not infringe the '584 patent, immediately stipulated that it would not bring an infringement claim as to the reformulated product. In addition, the two firms settled the pending patent case (neither abandoning its position regarding infringement) and terminated the Agreement, although petitioner agreed not to market the generic versions of Cardizem CD at issue in the patent case without a license from HMR. *Id.* at 44a-45a. By that time, HMR's payments to petitioner pursuant to the Agreement totaled $89.83 million. *Id.* at 18a. Two weeks later, petitioner began marketing its generic version of Cardizem CD at a price below that of HMR's brand-name product. *Id.* at 45a.

The Federal Trade Commission (FTC) investigated the Agreement, and in March 2000, issued an administrative complaint against petitioner, HMR, and Carderm, alleging that the Agreement was anticompetitive in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45. *In re Hoechst Marion Roussel, Inc., Carderm Capital L.P., & Andrx Corp. (In re HMR)*, No. 9293, Compl. (FTC Mar. 16, 2000) <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>. The matter was settled with a consent order providing prospective relief. Decision and Order (FTC May 11, 2001) <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. A subsequent ANDA filer also challenged the Agreement on antitrust grounds. *Andrx Pharm., Inc.* v. *Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 533 U.S. 931 (2002).

3. Respondents and other purchasers of pharmaceuticals filed suit[2] against petitioner and HMR, alleging that the Agreement was an unlawful restraint of trade under Section 1 of the Sherman Act, 15 U.S.C. 1. The core allegation was that the Agreement not only delayed the marketing of petitioner's generic product but also, because petitioner's exclusivity period would not expire until 180 days after petitioner entered the market, effectively precluded anyone else from bringing a generic form of Cardizem CD to market. Pet. App. 10a-11a.

4. The district court granted partial summary judgment in favor of the plaintiffs, holding that the defendants had entered into an "agreement between horizontal competitors that allocates the entire United States market for Cardizem CD and its bioequivalents to [HMR], and thus constitutes a restraint of trade that has long been held illegal *per se* under established Supreme Court precedent." Pet. App. 35a (citing *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46 (1990), and *United States* v. *Topco Assocs., Inc.*, 405 U.S. 596 (1972)). The court construed the Agreement "[o]n its face" to restrain petitioner from marketing not only "its generic version of Cardizem CD in July 1998 when FDA approval was expected and obtained," but also "other bioequivalent or generic versions of Cardizem CD which were not at issue in the pending [HMR]/Andrx patent case, including the reformulated generic drug described in its September 11, 1998 prior approval supplement to its ANDA." *Id.* at 65a; see also *id.* at 59a-60a, 61a. Thus, the court concluded, the Agreement "restrained [petitioner] from marketing non-infringing or potentially non-infringing versions of Cardizem CD." *Id.* at 65a. Moreover, by restraining petitioner from "relinquishing

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[2] The actions were consolidated for pretrial proceedings in the Eastern District of Michigan. Apparently, all parties other than petitioner and respondents here have reached settlements. Pet. App. 14a n.9; Pet. ii.

or otherwise compromising its right to the 180-day period of exclusivity," *ibid.*, the court found that the Agreement "allocated the entire United States market for Cardizem CD and its bioequivalents to [HMR] during the life of that Agreement." *Id.* at 66a. The court distinguished the Agreement from a patent license with territorial restrictions, such as that held not to offend the antitrust laws in *Dunlop Co.* v. *Kelsey-Hayes Co.*, 484 F.2d 407 (6th Cir. 1973), cert. denied, 415 U.S. 917 (1974), noting that the Agreement extended beyond allegedly infringing formulations. Pet. App. 74a-75a.

Two months after granting partial summary judgment, the district court certified the question of the per se status of the Agreement for interlocutory appeal pursuant to 28 U.S.C. 1292(b), along with an issue relating to defendants' motion to dismiss the plaintiffs' antitrust claims for failure to plead antitrust injury. C.A. App. 606 (Order No. 16). The court of appeals granted leave to appeal. Pet. App. 83a-85a.

5. The court of appeals held that the district court properly granted partial summary judgment for the plaintiffs as to the illegality of the Agreement, concluding that "[t]he Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem CD and its generic equivalents is a horizontal market allocation agreement and, as such, is *per se* illegal under the Sherman Act." Pet. App. 4a. The Agreement, the court of appeals explained, "was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." *Id.* at 18a. The court rejected the defendants' reliance on the fact that the Agreement arose in the context of patent infringment litigation, concluding that "the Agreement cannot be fairly characterized as merely an

attempt to enforce patent rights or an interim settlement of the patent litigation." *Id.* at 19a.[3]

DISCUSSION

Agreements settling patent infringement cases can raise difficult, important, and unsettled issues at the intersection of intellectual property law and antitrust law. A rule treating as a per se violation of the antitrust laws every patent infringement settlement agreement that precludes the marketing of allegedly infringing products in exchange for payments from the patentee to the alleged infringer (so called "reverse payments") would conflict with the well-established principle that per se treatment is reserved for conduct that has a predictable and pernicious anticompetitive effect.

This case, however, is not an appropriate vehicle for the Court to provide guidance as to the application of the antitrust laws to settlements in patent infringement cases involving reverse payments. The district court construed the Agreement at issue in this case to cover petitioner's marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation. Moreover, this case involves the relatively rare situation in which the parties entered into an *interim* agreement that did not resolve the parties' underlying patent dispute. These atypical aspects of the case militate against further review, particularly at this interlocutory stage.

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[3] After observing that the court's determination that the Agreement was illegal per se did "not resolve the issues of causation and damages," Pet. App. 21a, the court of appeals further held that the district court properly denied the defendants' motion to dismiss the complaint for failure to allege an antitrust injury. *Id.* at 4a, 21a-33a. Petitioner has not sought review of that holding.

I. Patent Infringement Settlements Precluding Entry By the Alleged Infringer In Exchange For Reverse Payments May Raise Antitrust Concerns, But Such Agreements Are Not Automatically Subject To Per Se Condemnation

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the public interest. Settlements of patent infringement claims are often predicated on an agreement that the alleged infringer will not make and sell the allegedly infringing product in competition with the patentee and its licensees, or that it will do so only pursuant to the terms of a license agreement. Were it not for the existence of the patent and the allegation of infringement, a court would likely treat such an agreement as an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. Indeed, but for the patent and the alleged infringement, the hypothetical settlement agreement would likely be seen as "a naked restrain[t] of trade with no purpose except stifling of competition," *Broadcast Music, Inc.* v. *CBS*, 441 U.S. 1, 20 (1979) (citation and internal quotation marks omitted), and therefore treated as unlawful per se based on its "predictable and pernicious anticompetitive effect" and its "limited potential for procompetitive benefit." *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997).

In the patent context, however, a settlement involving restrictions on the sale of allegedly infringing products is not necessarily anticompetitive. A patent grants the patent holder the lawful "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Thus, patent holders can lawfully refuse to license competitors to produce the patented article, or can grant exclusive territorial or other limited licenses to one or more chosen licensees. *Ibid.*; 35

U.S.C. 261, 271(d)(4); *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001).

At the same time, a restrictive agreement that occurs in connection with a patent litigation settlement is subject to antitrust scrutiny if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford," *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason for concern about the competitive consequences of a settlement that includes payments from the patent holder to the alleged infringer. Such reverse payments can be a device for the sharing of monopoly rents made possible by the alleged infringer's exclusion from the market and can result in less competition than would likely have prevailed in the absence of the payment. Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749 (2003); Carl Shapiro, *Antitrust limits to patent settlements*, 34 RAND J. Econ. 391, 408 (2003).

There is insufficient basis, however, for per se condemnation of all settlement agreements in patent infringement cases that preclude marketing of allegedly infringing products in exchange for payments from the patentee to the alleged infringer. Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare. For example, reverse payments may reflect a savings in the patent holder's expected litigation costs. Thus, consent orders entered into by the FTC reflect the view that payments to the alleged infringer up to the value of the patent holder's expected litigation costs in enforcing the patent are not anticompetitive.[4] The FTC has identified

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[4] *Bristol-Myers Squibb Co.*, No. C-4076 (FTC Apr. 14, 2003) (consent order), <http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf>;

other possible "legitimate justifications" for reverse payments, such as a "'cash starved' generic" drug firm that could productively use "some up-front support from the pioneer manufacturer," a "generic challenger [that] is more optimistic about the litigation outcome than the pioneer," "widely differing risk preferences," and a "judgment-proof generic manufacturer [whose] downside risks of damage exposure are small." *In re Schering-Plough Corp.* (*Schering*), No. 9297 (FTC Dec. 18, 2003), slip op. 37-38 (<http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>), appeal docketed, No. 04-10688-AA (11th Cir. filed Feb. 13, 2004); see also Shapiro, *supra*, 34 RAND J. Econ. at 408 & n.29 (citing risk aversion and asymmetric information about market conditions).

At the same time, a rule of reason analysis permits antitrust liability to attach to patent settlements involving reverse payments in appropriate circumstances. Applying a rule of reason analysis and based on a fully litigated factual record, the FTC condemned the settlements in the *Schering* decision, finding that the patentee paid the generic firms to defer their entry; that the entry of those lower-cost generics would be a "direct consumer benefit" (*Schering*, slip op. 20); that the payments were not ancillary to a pro-competitive

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Schering-Plough, No. 9297 (FTC Apr. 3, 2002) (consent order as to American Home Products Corp.), <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>. Commentators generally take this position as well. See, *e.g.*, Hovenkamp, *supra*, 87 Minn. L. Rev. at 1759; Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1802 (2003); Shapiro, *supra*, 34 RAND J. Econ. at 407-408; Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1767, 1782, 1787 (2003) (distinguishing expected litigation costs from other collateral costs and from considerations of patent validity).

settlement; and accordingly that such agreements were anticompetitive. *Id.* at 25, 26, 31. As the FTC observed, in a settlement without a reverse payment, it is reasonable to infer that the settlement reflects the parties' expectations about the outcome of the patent litigation. As a result, any restraint upon entry by the generic applicant results from its views of the patent's strength. By contrast, a reverse payment can enable competitors to share the profits created by the generic firm's non-entry into the market. The FTC has thus concluded that, unless there are offsetting pro-competitive considerations, an agreement involving a payment from the patentee to an alleged infringer logically results in a later generic entry date and less competition than would be expected absent the payment. *Id.* at 26.

II. The Sixth Circuit's Decision Involves An Agreement That Has Been Construed To Exclude Non-Infringing and Potentially Non-Infringing Products And Does Not Squarely Conflict With The Eleventh Circuit's Decision In *Valley Drug*

The petition seeks (Pet. 7, 9-18) to have this Court resolve an alleged conflict between the decision below and the subsequent decision in *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), petition for cert. pending, No. 03-1178 (filed Feb. 13, 2004), conditional petition for cert. pending sub nom. *Walgreen Co.* v. *Abbott Laboratories*, No. 03-1175 (filed Feb. 16, 2004). The two decisions, however, do not present a square conflict that necessitates this Court's review at this time. The Eleventh Circuit in *Valley Drug* rejected the characterization of interim patent settlement agreements as per se illegal, but relied on the fact that the parties agreed that the ANDAs that were the subjects of the infringement suits *admittedly infringed* a patent. 344 F.3d at 1304-1306 & n.18. The Eleventh Circuit recognized that the agreements before it

were also alleged to prohibit the marketing of *non-infringing* products and to prohibit the waiving of the ANDA filer's 180-day exclusivity period. With respect to those allegations, however, the court stated that "th[o]se prohibitions may be beyond the scope of [the patent's holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions." *Id.* at 1306 n.18; cf. *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 456 (1940). The Eleventh Circuit's rejection of a per se rule was thus addressed to "the failure * * * to market *admittedly infringing* products." 344 F.3d at 1306 n.18 (emphasis added).

It is less than clear that the Sixth Circuit's decision departs from the holding in *Valley Drug*. The better reading of the Sixth Circuit's opinion is that it does not deem illegal per se every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product. To be sure, petitioner and its amici point to seemingly broad language in the Sixth Circuit's opinion that they construe to require application of a per se rule in such circumstances. See, *e.g.*, Pet. 10 (citing Pet. App. 18a); Am. Intell. Prop. Law Ass'n Amicus Br. (AIPLA Br.) at 2-3. If construed in that manner, the court of appeals' decision would be erroneous. As discussed, a per se rule is reserved for the limited instance in which an exclusion from the market has "such predictable and pernicious anticompetitive effect" that "experience with [that] particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." *State Oil Co.*, 522 U.S. at 10 (citation omitted). Certain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate.

The Sixth Circuit's opinion is better read, however, as limited to the particular agreement before the court, which had been construed by the district court to restrain petitioner "from marketing *non-infringing* or *potentially non-infringing* versions of Cardizem CD," thus reaching versions "not at issue in the * * * patent case, including" the non-infringing reformulated generic drug that the FDA approved and petitioner eventually marketed. Pet. App. 65a (emphasis added); accord *id.* at 59a-61a. The FTC's complaint similarly had construed the agreement to restrain petitioner "from selling any other bioequivalent or generic version of Cardizem CD, regardless of whether such product would infringe Hoechst MRI's or Carderm's patents." *In re HMR*, *supra*, Compl. at ¶ 23. The district court moreover found that the Agreement restrained Andrx from "relinquishing or otherwise compromising its right to the 180-day period of exclusivity," thereby possibly delaying entry by other generic firms. Pet. App. 65a. Both of those restraints extended beyond the legitimate scope of the patent claims by reaching non-infringing products and conduct by petitioner that the patent conferred no right to exclude or demand.[5]

The district court rejected petitioner's arguments that the challenged provisions should be treated as ancillary to a lawful agreement, Pet. App. 75a-81a,[6] and concluded that, as

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[5] In its *Schering* decision, the FTC observed that the Sixth Circuit "found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry," whereas the Eleventh Circuit in *Valley Drug* "expressly considered contrary authority and declined to apply the *per se* label." *Schering*, slip op. 12-13. The FTC noted, however, that the Sixth Circuit's decision "can be distinguished on its facts" because "there were additional potentially anticompetitive commitments by the generic." *Id.* at 13 n.26.

[6] An agreement not to compete that is ancillary to a lawful agreement is properly analyzed under the rule of reason, rather than the per se rule. Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for*

construed, it constituted a per se violation of the antitrust laws. Whether or not the district court's conclusions as to ancillarity and the applicability of the Agreement to non-infringing products are correct, it is hardly novel to condemn as illegal per se an agreement between an incumbent and a potential competitor that is not ancillary to any lawful agreement and that precludes the potential competitor from entering the market with a product that does not infringe any patent owned by the incumbent. See Hovenkamp, *supra*, 87 Minn. L. Rev. at 1764-1765 ("While the language in the [district court's] opinion is a little opaque, if it meant that Andrx promised not to sell products that Cardizem did not claim in its patent to begin with, then that portion of the agreement was per se unlawful notwithstanding the presence of a patent dispute.").

The court of appeals gave no indication that it departed from the district court's analysis, and its opinion suggests that it relied on the district court's construction of the Agreement. Thus, in rejecting petitioner's "attempts to avoid *per se* treatment," the court of appeals stated that "the Agreement cannot be fairly characterized as merely an attempt to enforce patent rights or an interim settlement of the patent litigation," "*[a]s explained in greater detail in the district court's opinion.*" Pet. App. 18a-19a (emphasis added). The court then cited a portion of the district court's opinion (*id.* at 19a, citing *id.* at 67a-80a) that included the district court's determinations that the Agreement extended to non-infringing versions, *id.* at 77a, 79a, and in effect excluded other competitors, *id.* at 77a, 80a. Moreover, in footnote 13

Collaborations Among Competitors § 3.2 (Apr. 2000) <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 3.4 (Apr. 1995) <http://www.usdoj.gov/atr/public/guidelines/ipguide.pdf>.

of its opinion (*id.* at 19a n.13), the court cited to a discussion in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 241 (E.D.N.Y. 2003), that specifically referenced the district court's reliance in this case on the Agreement's coverage of two products that were not at issue in the pending patent litigation.

In *Valley Drug*, the Eleventh Circuit was properly hesitant to recognize a square conflict between the two decisions. The Eleventh Circuit thus noted that the Sixth Circuit may have been influenced not only by the Agreement's provisions for reverse payments but also "by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent." 344 F.3d at 1311 n.26.[7] Given the uncertainty over the scope and impact of the Sixth Circuit's decision, review at this time may be premature.

III. The Sixth Circuit's Decision Involves An Unusual Context—An Interim Patent Settlement Agreement—That Has Not Occurred With Significant Frequency

Petitioner also argues (Pet. 19-27) that the Court's review of the question whether interim agreements are unlawful per se is warranted because the issue is one of great and recurring importance. Settlements with reverse payments in an amount far exceeding litigation costs (such as the agree-

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[7] To be sure, the Eleventh Circuit also criticized the Sixth Circuit for failing "to measure the several provisions [of the Agreement] against the exclusionary power of the patents, or differentiate between provisions that fell within the scope of the patent's protection and those which did not." 344 F.3d at 1311 n.26. But the Sixth Circuit did not expressly preclude such an inquiry, and indeed, to the extent the court's approval of per se treatment rests on the Agreement's coverage of non-infringing or potentially non-infringing products, that reasoning would suggest a need for precisely such an inquiry to be conducted on remand. In any event, there is as yet no clear conflict on this issue.

ment in this case), however, appear to be rare outside the Hatch-Waxman context. Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1797-1798, 1800 (2003). A variety of factors unique to the pharmaceutical industry, including the effects of state laws and various policies of health care institutions that accelerate and magnify the economic impact of generic entry and the contours of the Hatch-Waxman regulatory scheme, have created incentives for the use of reverse payment provisions in pharmaceutical patent litigation. For example, reverse payment settlements may be attractive to the patentee in this context because they may forestall entry not only by the alleged infringer, but by other generic firms as well. Hovenkamp, *supra*, 87 Minn. L. Rev. at 1757.

More significantly, the question presented by petitioner appears to have limited significance even in the Hatch-Waxman context because this case involves an *interim* settlement agreement that did not finally resolve the parties' underlying patent dispute. After undertaking an exhaustive study of litigation agreements over an eight-year period relating to drug products for which paragraph IV certifications have been filed, the FTC has found such interim agreements to be rare. Aside from the agreements challenged here and in *Valley Drug*, the FTC study found only one other interim agreement between a patentee and an alleged infringer, and no such agreements entered into after the FTC's investigations in this area became public in April 1999. Federal Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 34 (July 2002) <

Such interim settlement agreements are particularly unlikely given that the Hatch-Waxman Act effectively grants an automatic 30-month preliminary injunction in favor of a

patent holder that timely files an infringement action. Under 21 U.S.C. 355(j)(5)(B)(iii), the FDA is barred from approving the alleged infringer's ANDA for 30 months, thus blocking the generic drug's entry, unless the patent on the pioneer drug is judicially declared invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iii).[8] In contrast to the agreements in this case and in *Valley Drug*, all of the decisions pending in the lower courts cited by petitioner (Pet. 13-16) involve final settlements that conclusively resolve the parties' patent dispute. The distinction is important because the calculus of competitive costs and benefits is substantially different for interim settlements and final settlements. While final settlements of infringement claims may have anticompetitive effects, they may "facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights." AIPLA Br. at 14. The type of interim agreement at issue in this case, on the other hand, may have none of those effects, because it leaves questions of patent validity and infringement to be litigated. Consequently, this Court's consideration of the question presented might be of limited practical importance and would

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[8] The interim agreements at issue in this case and in *Valley Drug* arose from peculiar circumstances in which the automatic 30-month stay that is ordinarily available to the patent holder was not in place. In the present case, HMR did not sue a later ANDA filer, Biovail, for infringement, *Andrx Pharmaceuticals, Inc.* v. *Biovail Corp.*, 256 F.3d at 803, and thus the automatic 30-month stay on FDA approval that an infringement suit would have triggered did not arise against Biovail's ANDA. Petitioner's 180-day exclusivity rights, however, could still block Biovail's entry into the market, and the Agreement was entered just a few months after Biovail filed its ANDA. In *Valley Drug*, the patent holder, Abbott, failed to file an infringement suit with respect to one ANDA within the statutory period necessary to trigger the 30-month stay on FDA approval. The parties entered into their interim agreements shortly after the generic firm received final approval by the FDA with respect to the product not subject to the 30-month stay. 344 F.3d at 1299.

not necessarily offer guidance regarding the antitrust liability that may attach to final patent infringement settlements.

IV. Subsequent Amendments To The Hatch-Waxman Act Militate Against This Court's Review Of The Sixth Circuit's Decision At This Time

This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003, after the parties entered into the agreements at issue in this case and in *Valley Drug*. Those amendments provide that the Act's 180-day exclusivity will be awarded on a product basis, rather than a patent-by-patent basis, Pub. L. No. 108-173, § 1102, 117 Stat. 2458 (to be codified at 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)), and permit all ANDA applicants that filed on the first day that an ANDA could be filed to be eligible for the 180-day exclusivity period, 117 Stat. 2457 (to be codified at 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb)). The former change may reduce the number of times that the FDA may grant the 180-day exclusivity to a company that has filed the first ANDA containing a paragraph IV certification. The latter change, by allowing multiple ANDA applicants to obtain the 180-day exclusivity period, may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments.

Congress also amended the Act to require pioneer drug companies and generic applicants to file all patent settlement agreements and certain other agreements with the U.S. Department of Justice and the FTC within 10 days of execution. §§ 1111-1117, 117 Stat. 2461-2463. Because the amendments are complex and relatively new, it is not yet clear how they will affect competitive concerns relating to interim agree-

ments between pioneer and generic drug manufacturers. Accordingly, review by the Court of the question presented may be premature.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 03-779

IN THE

Supreme Court of the United States

Andrx Pharmaceuticals, Inc., *Petitioner,*

v.

The Kroger Co., Albertson's, Inc., Hy-Vee, Inc., The Stop & Shop Supermarket Co., Walgreen Co., Eckerd Corp., CVS Meridian, Inc., and Rite Aid Corp., *et al.*, *Respondents.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

The American Intellectual Property Law Association ("AIPLA") respectfully moves for leave to file the attached *amicus curiae* brief, pursuant to Supreme Court Rule 37.2(b), in favor of granting the petition for a writ of *certiorari*.

The AIPLA is a national bar association of more than 15,000 members with interests and practices primarily in the areas of patent, trademark, copyright, trade secret, and other areas of intellectual property law. Unlike areas of practice in which separate and distinct plaintiffs' and defendants' bars exist, most intellectual property lawyers represent both intellectual property owners and alleged infringers.

The Court should grant the AIPLA leave to file the attached *amicus curiae* brief, because—through its diverse representation of the intellectual property bar—it brings a broad perspective and extensive experience to the important issues raised below by the decision of the Sixth Circuit Court of Appeals. Those issues are vital to intellectual property owners, licensees, and the judicial system, because they affect parties engaged in settling patent litigations and licensing patents. The decision below strikes at principles that form the foundation for patent protection and the intersection of patent and antitrust law.

The AIPLA seeks to bring to the Court's attention highly relevant information on those issues. The AIPLA's information should be of considerable help to the Court in resolving the split on these issues between circuit courts of appeals. The Sixth Circuit's decision directly conflicts with a decision of the Eleventh Circuit. It also implicates a conflict

with patent misuse case law from the Federal Circuit and directly conflicts with a recent decision of the Federal Trade Commission. In resolving that split, the Court should have the benefit of the AIPLA's perspective and experience, which none of the individual parties below can provide.

The AIPLA sought consent to file an *amicus curiae* brief from the counsel of record for all parties, pursuant to Supreme Court Rule 37.2(a). Counsel for Petitioner (a defendant in the case below) and counsel for certain Respondents (plaintiffs-below) consented.[1] Counsel for certain other Respondents, however, did not consent to the AIPLA's filing a brief, and counsel for some other Respondents did not respond to the AIPLA's request.[2] Copies

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[1] Counsel for the following Respondents provided written consent to the AIPLA's filing an *amicus curiae* brief: CVS Meridian, Inc.; and Rite-Aid Corp. Counsel for the following Respondents orally informed the AIPLA's counsel of record that they consented, but did not indicate in writing whether they consented: The Kroger Co.; Albertson's, Inc.; Hy-Vee, Inc.; The Stop & Shop Supermarket Co.; Walgreen Co.; and Eckerd Corp. Additionally, counsel for co-defendant-below, Aventis Pharmaceuticals, Inc., provided written consent, although Aventis is not a party to the decision that is the subject of the instant petition.

[2] Counsel for the following Respondents did not consent to the AIPLA's filing an *amicus curiae* brief: Charles Zuccarini; Joseph D'Esposito; Shirlean Glover; Larry S. Sizemore; Albert Eirich; Aetna, Inc.; and Cobalt Corp. Counsel for one Respondent, Eugienia Wynee Sams, responded that his client is not in a position either to consent or to object to the AIPLA's filing such a brief. Counsel for the following Respondents did not respond to the AIPLA's request for consent, as of the date of this filing: Duane Reade, Inc.; and Louisiana Wholesale Drug Co.

of the responses received from the parties are being filed with the Clerk.

Accordingly, the AIPLA respectfully requests that the Court grant the AIPLA's motion for leave to file the attached *amicus curiae* brief.

Respectfully submitted,

Dated: December 29, 2003

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STATEMENT OF INTEREST[3]

The AIPLA has no interest in any party to this litigation or stake in the outcome of this case, other than its interest in seeking a correct and consistent interpretation of the law affecting intellectual property.

SUMMARY OF ARGUMENT

The Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003) (hereafter "*Cardizem*") imposed *per se* antitrust illegality for an agreement to settle patent litigation in which the patent owner gave consideration to the alleged infringer in exchange for an agreement not to practice the patent before patent expiration. Although the specific facts of the case relate to pharmaceutical companies settling litigation under the Hatch-Waxman Act, the detrimental effect of the Sixth Circuit's *per se* rule extends to all patent settlements and license agreements in all industries. The Sixth Circuit focused on monetary payments. But the implications are that any type of consideration flowing from a patentee to a potential infringer as part of the overall agreement would render the agreement *per se* illegal.

The Sixth Circuit's *per se* holding conflicts directly with the subsequent decisions of the Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), and the Federal Trade Commission in *In re*

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[3] In accordance with Supreme Court Rule 37.6, the AIPLA states that this brief was not authored, in whole or in part, by counsel to a party to the instant petition, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the AIPLA or its counsel.

Schering-Plough Corp., Dkt. No. 9297, 2003 WL 22989651, at *10-*11 (FTC Dec. 8, 2003). Both subsequent decisions held that patent settlement agreements in which the patent owners made alleged "reverse payments" to the accused infringers, *i.e.*, where the patent owner provided consideration to the accused infringer in exchange for an agreement that the accused infringer will not practice the patent in dispute, should be judged under the Rule of Reason, not the *per se* rule. In addition, the Sixth Circuit's decision implicates a conflict with the Federal Circuit's case law regarding patent misuse, which evaluates such restrictions under the Rule of Reason. *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706-08 (Fed. Cir. 1992).

The AIPLA takes no position on the merits of this case or who should prevail on the instant facts under a Rule of Reason analysis. Instead, the AIPLA strongly believes that the Rule of Reason should provide the structure for the analysis, rather than the *per se* rule.

This is an important issue with widespread impact on numerous parties to all types of patent settlements and licenses, upon which two courts of appeals have directly conflicting opinions. For this reason, the AIPLA urges the Court to grant the petition for *certiorari* to resolve the conflict.

ARGUMENT

I. The *Per Se* Illegality Rule the Sixth Circuit Announced in *Cardizem* Will Have Grave Consequences for Patent Owners, Alleged Infringers, and Patent Licensees

In *Cardizem*, the Sixth Circuit ruled that a patent infringement settlement was, "at its core, a horizontal agreement to eliminate competition in the market for [the patent owner's product] throughout the United States, a classic

example of a *per se* illegal restraint of trade." 332 F.3d at 908. The "core" provision on which the court focused was the accused infringer's agreement not to sell its allegedly infringing product in the United States—*i.e.*, not to practice the patent—during a portion of the patent's term, in exchange for consideration from the patent owner. *See id.*, 332 F.3d at 907-08.

The case arose in the context of settlement of patent infringement litigation between a brand-name pharmaceutical manufacturer and a potential generic drug competitor under the "Hatch-Waxman Act." Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The implications of the *per se* rule that the Sixth Circuit established, however, reach far beyond that context. It calls into question the legality of commonly accepted provisions in patent settlement and license agreements that historically have been judged under the Rule of Reason.

The effect of the Sixth Circuit opinion is not limited to just the settlement of patent infringement litigations. The decision found the agreement *per se* illegal without considering the procompetitive justification, *i.e.*, it settled litigation. *See Cardizem*, 332 F.3d at 908-09. The *Cardizem* rule thus implicates provisions in commercial patent licenses in all contexts, in agreements to settle other types of patent suits and interferences, and in agreements reached to resolve disputes before litigation begins, where any consideration flows from the patent owner to the alleged infringer.

Accused infringers who decide to end patent infringement litigation often agree to the full injunctive relief available to the patent owner under the Patent Code. *See* 35 U.S.C. § 283 (2000). They agree not to practice the patent—*i.e.*, not to make, use, sell, offer to sell, or import the allegedly infringing product or process—anywhere in the United States

during the patent term. Often they do so in exchange for consideration by the patentee, *e.g.*, cessation of litigation and forgiveness of damages.[4]

Other routine settlement agreements and licenses often permit the potential infringer to practice the patent only within a certain scope limited by, for example, geographic territory or field of use, in exchange, at least in part, for a contractual equivalent of an injunction for the remaining scope of the patent.[5] Such restrictions traditionally have been evaluated

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[4] *See, e.g.*, Raymond C. Nordhaus, *Patent License Agreements: Law and Forms*, Forms 57.01-57.03, at 57-5 (2d ed. 1986), which gives examples of such a provision, including (Form 57.01):

> XYZ agrees to hereafter avoid any and all infringement, directly or indirectly, of said Letters Patent, either by the manufacture of products of the forms particularly complained of by ABC and sold by XYZ or otherwise.
>
> ABC hereby releases XYZ and its customers from any claim of infringement of said Letters Patent arising prior to the effective date of this Agreement, such release being conditioned upon the continued observance by XYZ of its obligation not to infringe said Letters patent hereafter.

[5] *See, e.g.*, Brian G. Brunsvold & Dennis P. O'Reilley, *Drafting Patent License Agreements* (4th ed. 1998), which gives examples of such provisions:

> LICENSOR hereby grants to LICENSEE, to the extent of the LICENSED FIELD and LICENSED TERRITORY, a license under PATENTS and IMPROVEMENTS to make, use, offer to sell, sell, and import LICENSED PRODUCTS. LICENSEE acknowledges and agrees that no license is granted or implied under, and agrees not to practice under,

footnote continued ...

under the Rule of Reason. *See, e.g., Brownell v. Ketcham Wire & Mfg. Co.*, 211 F.2d 121, 129 (9th Cir. 1954) (holding that an agreement that a licensee under a United States patent "will not sell or export" to any foreign country any products made under the license was "an agreement by [the licensee] to honor the territorial limits of the license granted, and was lawful" under the antitrust laws); *Miller Insituform, Inc. v. Insituform of N. America, Inc.*, 605 F. Supp. 1125, 1130-31, 1130 n.3 (M.D. Tenn. 1985), *aff'd*, 830 F.2d 606 (6th Cir. 1987) (district court holding as a matter of law that patent licensor's use of geographic restrictions in sublicensing its patent within the United States is immunized from antitrust liability under 35 U.S.C. § 261 (2000), but in any event is subject to analysis under the Rule of Reason rather than the *per se* rule; Sixth Circuit affirming and holding that patent owner did not violate Sherman Act § 2, 15 U.S.C. § 2, by exercising its patent right to exclude a former licensee from practicing the patent); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1132-35 (D.C. Cir. 1981) (upholding field of use restriction under Rule of Reason and

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> PATENTS and IMPROVEMENTS outside the LICENSED FIELD and LICENSED TERRITORY.

Appendix E, provision 3.0, at 287.

> LICENSEE acknowledges and agrees that the rights granted to it under this Agreement are limited to the licenses granted in paragraphs ___ and ___ hereof. LICENSEE acknowledges that the grant of those rights are conditioned on its agreement to refrain from using LICENSED PATENTS or LICENSED TECHNOLOGY outside the LICENSED FIELD and the LICENSED TERRITORY and that any such activity by LICENSEE shall be a material breach of this Agreement.

Form 17.00 B at 162.

rejecting *per se* rule); *see also Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938) ("The practice of granting licenses for a restricted use is an old one. . . . So far as appears, its legality has never been questioned.").

Despite the Rule of Reason treatment historically given to these common provisions, the principle of the Sixth Circuit's *per se* rule would condemn them categorically, because consideration flows from the patent owner to the accused infringer in exchange for an agreement not to practice the patent, in whole or in part. This principle introduces enormous uncertainty into routine agreements.

It is entirely unclear, for example, what kinds of compensation would trigger *per se* liability. The flow of consideration from the patent owner to the alleged infringer is inevitable in any patent settlement. Indeed, contracts require the exchange of some consideration to be enforceable. *See* Restatement (Second) of Contracts § 17 (1981); *see also Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, No. 03-C-3646, 2003 WL 22462405, at *6 (N.D. Ill. Oct. 29, 2003) (Posner, J., sitting by designation) (explaining that "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.")

Such "compensation" may take the form of, for example, a license with a favorable royalty arrangement, a cross-licensing opportunity, settlement of patent disputes in other countries, reimbursement of attorneys' fees, or surrender of a claim for money damages. Given the multitude of arguable benefits to a licensee in any licensing arrangement, a principle that relies on the receipt of consideration by the licensee as a hallmark of *per se* illegality "would appear to be quite difficult [if not impossible] to contain." *Broadcast*

Music, Inc. v. Columbia Broadcast Sys., Inc., 441 U.S. 1, 16 (1979) (hereafter "*BMI*").

Even if the *per se* rule were to apply only to cash payments, such as were involved in *Cardizem*, the Sixth Circuit's decision would raise a number of important questions. The *Cardizem* decision creates a *per se* rule without regard to the possible *pro*-competitive effect of settlement and without regard to the possible implications of the decision outside of the Hatch-Waxman Act structure. As the Federal Trade Commission recently pointed out, in the same Hatch-Waxman Act context as the instant case, agreements that include such payments "can be procompetitive in limited circumstances," for example, by providing needed capital to fund development of a new product. *Schering-Plough*, 2003 WL 22989651, at *11. Other questions would arise as well. For example, should there be an exception for payments limited to the nuisance value of the lawsuit? Should the rule be applied to payments that do not exceed the amount the defendant might have earned if it had prevailed in the lawsuit? Or should the rule apply only to payments that constitute sharing of monopoly rents? The Sixth Circuit's decision either leaves these questions unanswered, or it answers that they do not matter. The Sixth Circuit's rule thus fails to serve the policy objectives of "business certainty and litigation efficiency" that underlie the *per se* rule. *Arizona v. Maricopa Cty. Med. Soc.*, 457 U.S. 332, 343-44 (1982). If the receipt of consideration by the licensee has any relevance at all, its relevance can only be sensibly judged under the Rule of Reason.

The effect of the Sixth Circuit's rule extends beyond the Hatch-Waxman Act context and the pharmaceutical industry. As the Sixth Circuit itself recognized, the *per se* rule "establishes one uniform rule applicable to all industries alike." *Cardizem*, 332 F.3d at 908 (quoting *Arizona*, 457 U.S.

at 349, in turn quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 222 (1940)). Thus, by applying the *per se* rule to all patent settlements in "all industries alike," the Sixth Circuit's decision will cause a chilling effect, inhibiting any compromise and dispute resolution by parties in other contexts.

The Sixth Circuit's rule also undermines the enforceability of patents. By applying the *per se* rule to agreements that would otherwise pass muster under the Rule of Reason, the *Cardizem* rule can increase the number of patents that become unenforceable. *Per se* antitrust violations are considered misuse, rendering the patents unenforceable until the misuse is purged. *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706, 708 (Fed. Cir. 1992); *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir. 1986); *see also Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491-93 (1942).

Finally, the rule may have retroactive effect on large numbers of patent owners who agreed, in a settlement or license, not to practice the patent to some extent during its term in exchange for consideration. *See Harper v. Va. Dept. of Taxation,* 509 U.S. 86, 97-98 (1993) (explaining that newly announced rule of federal law applies retroactively unless court reserves the question of the applicability of the new rule to parties before it); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1370 n.4 (Fed. Cir. 2003) (applying newly established presumption under doctrine of equivalents "to all granted patents and to all pending litigation that has not been concluded with a final judgment, including appeals.").

This uncertain state of affairs creates a substantial risk of treble damages for parties to patent settlement and licensing agreements throughout the country, invalidation of those

agreements, and unenforceability of underlying patents. The outcome of any antitrust challenge to the agreements will depend on where the parties are sued and, if outside of the Sixth and Eleventh Circuits, which of these two competing rules will be applied. The result will be a powerful deterrent to legitimate business arrangements. A corresponding reduction in the number of patent settlements and licenses, and in the efficiency of those transactions, likely will follow. *See Bus. Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 728 (1988) ("Manufacturers would be likely to forgo legitimate and competitively useful conduct rather than risk treble damages and perhaps even criminal penalties."). This deterrent effect is intensified by the increasing prevalence of antitrust class action suits attacking patent settlement and licensing agreements, as this case and others cited in the Petition attest. *See* Petition for Writ of *Certiorari, Andrx Pharmaceuticals, Inc. v. The Kroger Co.*, Dkt. No. 03-779, at 13 (filed in S. Ct. Nov. 28, 2003).

In sum, the far-reaching effects of the Sixth Circuit's *per se* rule decision provide compelling reasons for review by this Court.

II. The *Cardizem* Decision Threatens To Upset the Proper Balance Between Patent Law and Antitrust Law, and Conflicts with Established Federal Circuit Law on Patent Misuse

"The essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see* 35 U.S.C. § 154(a)(1)(2000) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others . . . ."). Ignoring the patent law, the Sixth Circuit looked only to antitrust law, *Cardizem*, 332 F.3d at 906-09, contrary to this Court's instructions to balance the two: "The

patent laws . . . are in *pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil Co. of Calif.*, 377 U.S. 13, 24 (1964); *see Dawson*, 448 U.S. at 221 ("The policy of free competition runs deep in our law. . . . But the policy of stimulating invention that underlies the entire patent system runs no less deep.").

The Sixth Circuit's key finding that the settlement agreement was a horizontal agreement among competitors meant that it had to ignore the patent owner's fundamental legal right to exclude an infringer from practicing its patent.[6] This represents a fundamental shift in antitrust analysis. This Court has long maintained that antitrust analysis may not "ignore[] the privileges incident to ownership of patents." *Standard Oil Co. v. United States*, 283 U.S. 163, 172 (1931); *see Studiengesellschaft Kohle*, 670 F.2d at 1128-29 (explaining that it was error to determine anticompetitive effects without considering patent's exclusionary power).

A *per se* analysis that ignores the exclusionary power of the patent at issue has profound implications for all kinds of patent agreements. Under that principle, restrictions operating

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[6] In fact, the Sixth Circuit reached for the wrong label in branding the licensing arrangement a "horizontal agreement." The court was able to do so only by ignoring the exclusionary power of the patent that was the subject of the settlement—an approach that this Court has long condemned. *See, e.g., Standard Oil Co. v. United States*, 283 U.S. 163, 172 (1931). Had the court of appeals taken the patent rights into account, it would have had to conclude that the parties' relationship was vertical, not horizontal, for which a *per se* analysis would have been even less appropriate. *See* U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property, § 3.3 and Example 5, 1995 WL 229332, at *9-*10 (Apr. 6, 1995) (relationship is vertical if licensee could not have competed without a license from the patent owner).

within the scope of the patent, such as territorial or field of use restrictions discussed above, become subject to *per se* illegality.

Moreover, *Cardizem's per se* antitrust liability rule runs directly counter to the patent misuse rule applied by the Federal Circuit, which holds that restrictions within a patent's scope are *per se* not misuse. In *Mallinckrodt,* the Federal Circuit reaffirmed that "[r]estrictions on use are judged in terms of their relation to the patentee's right to exclude for all or part of the patent grant." 976 F.2d at 706. Accordingly, "[s]hould the restriction be found to be reasonably within the patent grant, *i.e.,* that it relates to subject matter within the scope of the patent claims, that ends the [misuse] inquiry." *Id.* at 708. Indeed, the Federal Circuit explained that even those restrictions that extend "beyond the patentee's statutory right to exclude" are evaluated for misuse under the Rule of Reason, unless they are *per se* antitrust violations. *Id.*

In contrast to the Sixth Circuit's *Cardizem* decision, and expressly disagreeing with *Cardizem's per se* rule, the Eleventh Circuit recognized these fundamental tenets of patent law in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1304-05, 1311 n.26 (11th Cir. 2003). The Eleventh Circuit understood that the exclusionary effect of the patent is "at the heart of the patent right and cannot trigger the *per se* label. . . . [T]he exclusion of infringing competition is the essence of the patent grant." *Id.* at 1306. Accordingly, in contrast to the Sixth Circuit's ignoring the effect of the patent, the Eleventh Circuit correctly concluded that "when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is *per se* illegal." *Id.* (quoting from *Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp.2d 188, 249 (E.D.N.Y. 2003)).

The Eleventh Circuit correctly states the rule that traditionally has applied and that the AIPLA respectfully urges should continue to apply.

III. The Sixth Circuit's Erroneous Application of the *Per Se* Rule Imperils Economically Beneficial Settlement and License Agreements

The "prevailing standard of analysis" under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2000), is the Rule of Reason. *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977) (hereafter "*Sylvania*"). A court applying the Rule of Reason would take into account all of the facts and circumstances surrounding the settlement, including the relative merits of the litigation positions and the unique regulatory overlay of the Hatch-Waxman Act.[7] More importantly, it would consider any procompetitive or efficiency effects of the settlement. But in applying the *per se* test, the Sixth Circuit refused to consider any potential benefits of the agreement. The court's failure to do so was a grievous error.

"*Per se* rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive."

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[7] One aspect of the Hatch-Waxman Act scheme is that in some situations a settlement agreement with the first generic drug applicant that has filed for FDA approval to market prior to patent expiration, and thereby obtained 180 days of market exclusivity under the Hatch-Waxman Act's provisions, can operate to delay the entry of later generic drug applicants, whereas settlements with subsequent generic filers would have no such effect. *See* David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L. J. 321, 334-35 (2000). Thus, the impact of any settlement on the statutory 180-day exclusivity period may be relevant and should be judged under a Rule of Reason analysis.

Sylvania, 433 U.S. at 49-50. Unless "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output," it does not qualify for *per se* treatment. *BMI*, 441 U.S. at 19-20. Practices that tend to increase economic efficiency, on the other hand, are governed by the Rule of Reason. *See id.* at 20; *Sylvania*, 433 U.S. at 54 (practices that achieve efficiencies have "redeeming virtues" that warrant Rule of Reason treatment); *Northwest Wholesale Stationers, Inc. v. Pac. Stationery and Prtg. Co.*, 472 U.S. 284, 290 (1985) (*per se* treatment is limited to those concerted refusals to deal that lack "any offsetting efficiency gains").

The Sixth Circuit condemned categorically under a novel *per se* rule settlement agreements and licensing provisions that do not meet these demanding criteria. However, the lack of long judicial experience with patent settlements involving "reverse payments," a feature that was critical to the court's *per se* conclusion, counsels against *per se* treatment. *See United States v. Topco Assoc., Inc.*, 405 U.S. 596, 607-08 (1972).

The Federal Trade Commission has also concluded that a *per se* approach was not appropriate for a patent settlement in the Hatch-Waxman Act context, where it found consideration was paid to the accused infringer in exchange for an agreement not to practice the patent. *See Schering-Plough*, 2003 WL 22989651 at *10-11. Indeed, the FTC believed that the Sixth Circuit's *Cardizem* opinion had not "taken adequate account of Supreme Court decisions that mandate a more nuanced approach. *See, e.g., California Dental Ass'n v. FTC*, 526 U.S. 756 (1999); *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984)." *Schering-Plough*, 2003 WL 22989651, at *49 n.26.

The probable result of the Sixth Circuit's decision will be to discourage many forms of settlement and license agreements that would deliver substantial economic benefits. Its impact will be felt most directly in the context of settlement agreements. The appellate court viewed the fact that the agreement settled patent litigation as "simply irrelevant" to its *per se* determination. *Cardizem*, 332 F.3d at 909. In so doing, it ignored the substantial economic benefits of patent settlements. Settlements facilitate innovation and investment in the patented technology by eliminating litigation risks and providing certainty over patent rights, and by freeing up for more productive uses resources that would otherwise be devoted to litigation. *See* James Langenfeld & Wenquing Li, *Intellectual Property Agreements To Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust Law Journal 777, 778 (2003). These efficiency-enhancing benefits further the goals of the antitrust laws, *see FTC v. Indiana Fed'n of Dentists,* 476 U.S. 447, 459 (1986) (efficiencies in the operation of a market or the provision of goods and services is a "procompetitive virtue"), and the patent laws, *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (uncertainty over scope of patent rights "would discourage invention only a little less than unequivocal foreclosure of the field" (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942))).

Settlement also serves an important public policy favoring resolution of disputes without litigation:

> Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and the

> citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.

Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976); *see E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 93 (1902) (settlement of patent litigation through license agreements is "a legitimate and desirable result in itself"); *St. Louis Mining & Milling Co. v. Montana Mining Co.*, 171 U.S. 650, 656 (1898) ("[S]ettlements of matters in litigation or in dispute without recourse to litigation are generally favored").

The court's rationale in striking down the settlement agreement, however, reaches far beyond the settlement context, for it would also outlaw commonly accepted contractual provisions, such as territorial and field of use restrictions in exchange for consideration from the patent owner, as discussed above. The potential procompetitive virtues of these kinds of provisions are well accepted and have been strongly endorsed by both federal antitrust agencies:

> Field-of-use, territorial, and other limitations on intellectual property licenses may serve procompetitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible. These various forms of exclusivity can be used to give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property and to develop additional applications for the licensed property.

U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property*, 1995 WL 229332, at *4 (April 6, 1995).[8]

These are but a few of the potential adverse consequences of the Sixth Circuit's expanded *per se* rule. The AIPLA respectfully submits that these consequences alone are sufficient to warrant review by this Court.

CONCLUSION

The Sixth Circuit's rule imposing *per se* antitrust liability for common restrictions within the scope of the patent grant is an important issue with widespread impact on patent settlements and licensing. It threatens to have a very significant and detrimental effect on the value of patents and their competitive benefits. The Sixth Circuit's decision directly conflicts with decisions from the Eleventh Circuit and the FTC, and implicates a conflict with case law on patent misuse from the Federal Circuit. This Court should resolve the conflict. Accordingly, the AIPLA respectfully urges this Court to grant the petition for *certiorari*.

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[8] The fact that the federal agencies charged with enforcing the antitrust laws endorse these benefits, while not dispositive, adds an additional cautionary note against *per se* treatment. *See BMI*, 441 U.S. at 16.

Respectfully submitted,

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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,
Petitioner,

v.

THE KROGER COMPANY, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Motion for Leave to File *Amicus Curiae* Brief and Brief for *Amicus Curiae* the Center for the Advancement of Capitalism in Support of Petitioner

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v.

THE KROGER COMPANY, ET AL.

Motion for Leave to File *Amicus Curiae* Brief

The Center for the Advancement of Capitalism (CAC), by its counsel and under Rule 37.2(b) of this Court's rules, respectfully requests leave to file the accompanying brief as *amicus curiae* in support of granting the petition for a writ of certiorari. Counsel for the petitioner, Andrx Pharmaceuticals, and counsel for Aventis Pharmaceuticals Inc. have consented to the filing of this brief. Andrx's counsel informed CAC that counsel for some of the respondents would not grant consent. None of the respondents have replied to CAC's requests for consent.

As set forth in the accompanying brief, CAC is a nonprofit organization that applies Ayn Rand's philosophy of Objectivism to contemporary public policy issues. CAC has particular expertise in the field of antitrust law, and our brief focuses on the potential impact of the decision below on the overall rights of businessmen in light of recent antitrust experiences.

CAC's brief succinctly addresses arguments not previously raised by Andrx. Accordingly, this brief will not

impose a substantial burden on the Court, and leave to file should be granted.

Respectfully Submitted,

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

INTEREST OF AMICUS CURIAE[1]

The Center for the Advancement of Capitalism ("CAC") is a District of Columbia corporation organized in 1998, and exempt from income tax under § 501(c)(4) of the Internal Revenue Code. CAC's mission is to present analyses to policymakers, the judiciary, and the public to assist them in the identification and protection of the individual rights of the American people. CAC applies Ayn Rand's philosophy of Objectivism to contemporary public policy issues and provides empirical studies and theoretical commentaries on the impact of legal and regulatory institutions upon the rights of American citizens.

CAC's mission is to advance philosophical and legal principles that promote individual rights, limited

[1] No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than CAC or its counsel, make a monetary contribution to the preparation or submission of this brief.

government, and capitalism. CAC has demanded the reexamination and ultimate abolition of the antitrust laws on practical, legal, and moral grounds—practically, because antitrust stifles production and harms consumers; legally, because antitrust abridges the rights of producers to trade what they make; and morally, because punishing successful production is unjust.

The instant case presents the question of whether the petitioner's patent infringement settlement results in a *per se* violation of the antitrust laws if the terms of the settlement do not provide the respondents with petitioner's generic alternatives to the patent-protected property. CAC believes that the decision below, if affirmed, will continue the erosion of property rights, including the right to enter and leave the market according to a businessman's self-interest and allow for even greater expansion of the evils of antitrust against businessmen. Because there are additional facts not addressed in the petitioner's petition that this Court should consider, CAC respectfully requests leave to file the accompanying brief containing discussion of this case.

SUMMARY OF ARGUMENT

The antitrust *per se* rule should not be expanded to include settlements, of any kind, between parties to a patent infringement settlement. This Court's previous decisions expanding the *per se* rule have had serious negative consequences on businessmen trying to live under the weight of conflicting antitrust mandates. For example, physicians subject to the *per se* rule have been effectively banned, under threat of antitrust prosecution, from negotiating contracts with managed care companies that reflect actual market prices. The result is a *de facto* price control on physician services. The same fate awaits pharmaceutical companies should the decision below in this case stand. Generic drug manufacturers in particular will be discouraged from entering the market since they face a

potential choice between risking costly patent infringement litigation on the one hand, and facing costly antitrust litigation on the other. This Court should not force companies to make such a fundamentally unfair and unreasonable choice.

ARGUMENT

The Sixth Circuit's decision should be reversed for the reasons stated by the petitioner, Andrx Pharmaceuticals. In addition, the Court should take this opportunity to reconsider the underlying antitrust principles that led to the Sixth Circuit's decision. This latest attempt to expand the *per se* rule neither clarifies the law nor advances antitrust's ostensible objective of protecting consumers. In its effort to create a judicial shortcut for class-action plaintiffs, the Sixth Circuit exposed key flaws in contemporary antitrust policy, and this Court should act to correct the errors before courts below inflict added damage.

Andrx and Aventis entered into two agreements that settled Aventis' Cardizem CD-related patent infringement claims. Under the first agreement, Aventis made quarterly payments to Andrx in exchange for Andrx's promise not to market generic Cardizem until the underlying patent litigation was concluded. The respondents in this case, all private purchasers of Cardizem, claim that this agreement violated their right to purchase Andrx's potential generic drug while the litigation was pending. Under the respondents' theory of "consumer rights," they were "denied" access to Andrx's generic drug between July, 1998, when Aventis' automatic 30-month stay under the Hatch-Waxman Act[2] expired, and June, 1999, when Andrx released Cartia XT, a Cardizem bioequivalent approved by the FDA and certified by Aventis as not infringing their patent. Moreover, in June of 1999, Aventis and Andrx signed a

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[2] 21 U.S.C. § 355.

second, final settlement disposing of all remaining patent infringement claims.

The respondents in this case (the plaintiffs below) claim that the first settlement was a *per se* antitrust violation because it amounted to a "naked, horizontal restraint of trade."[3] They argue that Andrx had a legal obligation to market generic Cardizem immediately upon receiving FDA approval, which was granted in August 1998, one month after the Hatch-Waxman stay expired. The respondents argue that consumer demand for a cheaper form of Cardizem overrode the threat that Andrx faced in marketing a product which infringed Aventis' patent. The Sixth Circuit essentially agreed with this premise, and held that Andrx committed a *per se* violation of the Sherman Act.

Under the government's current antitrust regime, businessmen are compelled to yield whenever the pursuit of their own interests may affect trade against the wishes of consumers. In this case, Andrx was confronted with a patent infringement suit. Rather then face months or years of resource-consuming litigation, Andrx reached an agreement with Aventis that satisfied both parties' interests. Subsequently, a number of third parties brought suit under the antitrust laws. The fundamental premise of their suit was that Andrx failed to sacrifice its interests to their needs.

In judging the respondents' antitrust claim, the Sixth Circuit applied a *per se* rule for one reason—misconceived judicial economy. If the enforcement of the Sherman Antitrust Act is ungainly, the responsibility rests with this Court for continuing to permit a statute that holds every transaction "in restraint of trade" to be illegal despite such a law's plain absurdity. Long antitrust trials are not the fault of businessmen who attempt to explain their conduct in terms of a larger understanding of the facts. They are the

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[3] Pet. App. 25a.

fault of a regimen that holds the rights of consumers above the rights of those who produce.

Yet, given the nature of antitrust, it is understandable why the labor-saving method of the *per se* rule appeals to the Court. Nevertheless, such interpretation presents the judiciary with a false alternative: violate the rights of businessmen quickly and easily versus a death by a thousand cuts. Neither interpretation is just. In keeping with the usual construction of antitrust law, this Court has reasoned that some antitrust violations are so obvious—even to "an observer with. . .a rudimentary understanding of economics"[4]—that consideration of the actual factual context of a case is unnecessary. According to this view, the courts may perform an extrapolation from their experience in dealing with certain classes of activities to declare that *all* instances of such activities are illegal *per se*. That is precisely what the Sixth Circuit did below—it dropped facts and context until all that remained was conveniently "conclusive proof" of Andrx's antitrust violation.

In turning back Andrx's request to consider the actual competitive effects of its agreement with Aventis, the Sixth Circuit clung to this Court's holding in *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982), which expanded the *per se* rule to include agreements among physicians to set fees jointly. The Sixth Circuit relied on a particular paragraph in *Marciopa*[5] which held that any attempt to question the *per se* rule's validity was, in essence, a waste of time and logic:

> The respondents' principal argument is that the per se rule is inapplicable because their agreements are alleged to have procompetitive justifications. The argument indicates a misunderstanding of the per se concept. The anticompetitive potential

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[4] *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

[5] *See* Pet. App. 20a.

> inherent in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. Those claims of enhanced competition are so unlikely to prove significant in any particular case that we adhere to the rule of law that is justified in its general application. Even when the respondents are given every benefit of the doubt, the limited record in this case is not inconsistent with the presumption that the respondents' agreements will not significantly enhance competition.[6]

The *Maricopa* doctrine emphasizes short term price competition as the objective of antitrust law. Accordingly, a defendant's claims of procompetitive benefits will generally fail when the government's objective is to ensure lower prices for the consumer in the short term. Andrx's procompetitive justifications failed in the courts below because nothing, according to antitrust doctrine, can ever justify a producer's intentional withholding of a product demanded by consumers, especially when that product is a low-cost alternative to an existing one.

Maricopa presents an ideal example of the *per se* rule in action. In that case, the Court dismissed the fact that the judiciary had "little antitrust experience in the healthcare industry"[7] and proceeded to strike down a common fee schedule arrangement that the dissent described as a "comparatively new method of providing insured medical services at predetermined maximum costs."[8] The Court ignored the new method, however, preferring rigid adherence to its *per se* doctrine:

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[6] *Maricopa*, 457 U.S. at 351.

[7] *Id.* at 349.

[8] *Id.* at 357 (Powell, J., dissenting).

> [T]he argument that the per se rule must be rejustified for every industry that has not been subject to significant antitrust litigation ignores the rationale for per se rules, which in part is to avoid "the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable - an inquiry so often wholly fruitless when undertaken."[9]

But there were consequences to the Court's decision not to undertake a "wholly fruitless" inquiry. When *Maricopa* was decided, physicians were not competing in a free market. By 1982, Congress had enacted legislation to cut federal expenditures for Medicare and Medicaid through what amounted to a governmental price-fixing scheme. Rather than permit the market to determine prices for physicians' services, Medicare and Medicaid set all prices on a take-it-or-leave-it basis. Following that lead, private managed care insurers (themselves the product of government intervention) adopted similar reimbursement schemes. CAC holds that these regulations were inherently unjust because Congress was consumed with cutting patients' costs at the expense of physicians.

Acting under *Maricopa*, the Federal Trade Commission and Department of Justice have used antitrust law to prevent physicians from acting in their rightful interest. Under current policy, "competing" physicians may not jointly negotiate contracts with managed care companies and other third-party payers. This is *per se* price fixing under *Maricopa*. The exception to this rule arises when physicians engage in financial "risk sharing," as defined by the

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[9] *Id.* at 351 (quoting *Northern Pacific R. Co. v. U.S.*, 356 U.S. 1, 5 (1958).

government. Currently, the FTC and DOJ allow two forms of risk sharing.[10] Neither model has proved to be financially viable for physicians; yet any deviation from these models subjects physicians to *per se* antitrust prosecution.[11]

Since 2001, the FTC and DOJ have brought civil charges against more than 11,000 physicians for illegal price fixing.[12] Most of the physicians denied wrongdoing, but settled to avoid the cost of civil litigation, not to mention potential criminal charges, since any *per se* antitrust violation can trigger the antitrust laws' criminal penalties.[13] In all of these cases, the government declared that physicians must negotiate with payers on their own, and not as a group. The government's position ignores both economic reality and the rights of physicians to the fruits of their own work. Individual physicians cannot negotiate meaningfully with multibillion-dollar insurance companies. Moreover, if enough physicians individually reject a proposed contract, the FTC and DOJ could infer a price-fixing conspiracy and bring charges. It follows that, under antitrust, the only genuine refuge for physicians is the acceptance of third-party contract offers without negotiation.

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[10] *See* U.S. Dep't of Justice and Federal Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996) (available at http://www.ftc.gov/reports/hlth3s.htm).

[11] For additional discussion of the FTC-DOJ policy and its impact, *see* Center for the Advancement of Capitalism, *Comments on the Proposed Consent Order in the Matter of Obstetrics & Gynecology Corp. of Napa Valley, et al.* (May 1, 2002) (available at http://www.capitalismcenter.org/Campaigns); Citizens for Voluntary Trade, *Comments on the Proposed Final Judgment in United States v. Mountain Health Care, P.A.*, 68 Fed. Reg. 44,577-44,591 (July 29, 2003).

[12] Citizens for Voluntary Trade, *Physician Groups Prosecuted by the FTC and DOJ Since 2001* (revised December 11, 2003) (available at http://www.voluntarytrade.org/physician_table.pdf).

[13] *See* Dep't of Justice, *United States Attorneys' Manual*, Title 7 ("virtually all antitrust offenses likely to be prosecuted by a United States Attorney's office will be governed by the per se rule") (available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title7/ant00007.htm).

The post-*Maricopa* physicians' market is a triumph of range-of-the-moment antitrust policy. Physicians are afraid to set their prices, and the *per se* rule allows regulators and the courts to remain ignorant of other factors affecting the market. But while the present system maintains the prosperity of managed care companies and the antitrust bar, the *Maricopa* doctrine has done nothing for the consumers of healthcare. No evidence demonstrates that insurance costs for individual customers are lowered by subjecting physicians to the *per se* rule. Indeed, physicians' costs have remained steady or declined in many markets, yet premiums have increased steadily and substantially. Had the *Maricopa* court not excused antitrust regulators from considering the competitive context of the entire market, policymakers might have reached a differing conclusion about the actions of physicians. By foreclosing all discussion of the issue in 1982, this Court effectively invited the FTC and DOJ to confer upon physicians the status of scapegoats for the continuing public policy problem of rising healthcare costs.

Andrx and the pharmaceutical industry are now at the crossroads faced by physicians in *Maricopa*. Drug manufacturers have become the most recent targets of legislative and executive displeasure over rising healthcare costs. Despite the unprecedented success of pharmaceutical companies in producing effective medicines, critics continue to focus on the antitrust theme of short-term price competition. As with physicians, *price fixation* excludes all other factors from the discussion. While total U.S. pharmaceutical outlays rose by more than 17% from 2000 to 2001, according to the NIHCM Foundation[14], these increases are not the product of price-fixing conspiracies hatched by pharmaceutical companies. Indeed, NIHCM found that only 37% of the 2001 cost rise was due to manufacturers' price

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[14] NIHCM Research & Education Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* at 4 (revised May 6, 2002) (available at http://www.nihcm.org/spending2001.pdf).

increases. The remaining 63% was attributed to the increased use of drugs and the shift to newer, more expensive medicines[15]: "Simply put, Americans are demanding, and physicians are prescribing, a higher volume of medicines each year."[16]

In addition, consumer demand is driven upward by government intervention in healthcare. The federal government accounts for over 45% of overall health spending in the U.S., and tax subsidies for private insurance health premiums account for another 10%.[17] When the government's drug costs increase, the pressure on the federal budget has led legislators and the White House to seek governmental solutions. For example, Congress recently passed statutes designed to incorporate prescription-drug benefits into Medicare.[18] Such statutes increase total government spending on drugs. CAC holds that when this spending inevitably reaches unsound and unsustainable levels, Congress will respond by shifting the responsibility to the pharmaceutical manufacturers in the form of price controls rather than by repealing its flawed benefit package.

Pharmaceutical companies are pressured to lower prices at the same time that they face increased regulatory burdens on their production. The development of new drugs is particularly costly. One study estimated that it takes 10 to 15 years and $802 million to bring a new drug through the system from conception, to research, to FDA approval.[19]

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[15] *Id.* at 6.

[16] NIHCM Research & Education Foundation, *Prescription Drug Expenditures in 2000: The Upward Trend Continues* at 9 (May 2001) (available at http://www.nihcm.org/spending2000.pdf).

[17] Doug Bandow, *Demonizing Drugmakers: The Political Assault on the Pharmaceutical Industry*, Cato Institute Policy Analysis No. 475 at 3 (May 8, 2003) (available at http://www.cato.org/pubs/pas/pa-475es.html).

[18] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (December 8, 2003).

[19] Bandow, *Demonizing Drugmakers* at 9.

Most of these costs are borne by the manufacturer and not by the government. Yet, when a new drug is patented, there is a near-instantaneous demand to bring a cheaper generic drug to market as quickly as possible. This is what led Andrx to develop a bioequivalent to Cardizem in the first place.

But Andrx cannot serve several masters simultaneously. It cannot seek to maximize profits and increase shareholder value while accommodating conflicting demands from government regulators and class-action attorneys who demand early access to a generic drug. In this case, Andrx's 1995 decision to produce generic Cardizem has cost it more than eight years of litigation: Aventis' patent infringement suit, followed by the FTC's 2001 antitrust investigation, and finally the class-action lawsuits that led to the petition now before this Court. If anything, this legal burden alone serves as a far greater restraint on competition than could any agreement between Andrx and Aventis.

Should this Court deny the petition or affirm the Sixth Circuit, it will send a message to generic drug manufacturers that their efforts may be better spent not competing. By subjecting some or all patent settlements to the *per se* rule, Andrx and its sister companies will face an unenviable choice in the future: Risk losing a patent infringement lawsuit, or settle and risk costly antitrust prosecution at the hands of numerous state attorneys general and a well-financed plaintiff's bar. Given this choice, many generic drug companies may exercise a third option taken by many physicians in the post-*Maricopa* era: They'll leave the market entirely.

The essence of the *per se* rule is the "but for..." mentality: "But for" Andrx and Aventis' agreement, the respondents argue, they would have had a cheaper drug sooner. Yet the one-year delay created by the Andrx-Aventis agreement is insignificant when compared with the government-imposed restraints on the pharmaceutical industry and the healthcare

market in general. This is why a *per se* rule cannot be applied reasonably. Without a fuller understanding of the true operative context of the marketplace, the courts will be reduced to making blind guesses as to what *might* happen in a given market under a limited set of objectively unwarranted assumptions. This fails to benefit consumers and violates the rights of producers. The mistakes of *Maricopa* are instructive. The Court has it within its power to set things right.

This case ultimately comes down to a question of property rights. Initially, Aventis sued Andrx over patent infringement. That issue was settled in accordance with established common and statutory law. By contrast, the respondents' case obliterates patent rights in the name of so-called "consumer rights" and obliterates Andrx's right to enter and leave the market for its own sake. If the Sixth Circuit's decision is allowed to trump the patent settlement, it will send an unmistakable message that this Court does not value property rights. CAC believes that such a message finds no support in the Constitution. The conflict between the Sixth and Eleventh circuits ought be resolved in favor of the latter and the Court should put the principle of property rights ahead of a judicial expansion of the *per se* rule.

CONCLUSION

For the reasons discussed above, and the reasons given by Andrx in its petition, the writ of certiorari should be granted.

Respectfully submitted,

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(3)

No. 03-779

IN THE
Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., AND RITE AID CORP., *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

MOTION OF NEW YORK INTELLECTUAL PROPERTY LAW ASSOCIATION AND BRIEF OF *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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The New York Intellectual Property Law Association ("NYIPLA") hereby moves, pursuant to Rule 37.2(b), for leave to file a brief *amicus curiae* in support of the petition for a writ of certiorari to the United States Court of Appeals for the Sixth Circuit. Petitioner and three of the six respondents have consented to the filing of this brief. We understand that the three remaining respondents have withheld their consent because they believe they are no longer interested parties.* A copy of the proposed *amicus* brief is attached.

As more fully explained at pages 1-4 of the attached brief under "Statement of Interest of *Amicus Curiae*", the NYIPLA is a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret, and other intellectual property law. The NYIPLA is, accordingly, well positioned to address the questions presented from the perspective of litigators who counsel businesses that own, enforce and challenge patents, as plaintiffs and defendants in patent litigation — including litigation arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act").**

The NYIPLA seeks to file the proposed brief to describe unresolved issues arising from the split between the Sixth and Eleventh Circuits regarding the legality of payments made by innovator pharmaceutical companies to their generic

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* Counsel for the NYIPLA made a first written request for consent on December 5, 2003 and repeated that request in writing on December 15, 2003. In response to those requests, the petitioner and three respondents consented in writing, and one respondent indicated by letter of December 16, 2003 that it no longer had an interest in the resolution of the case, but otherwise would have opposed the filing of the brief. We understand that the final two respondents oppose the filing of the brief, and also have stated that they are no longer interested parties.

** Pub. L. No. 98-417, 98 Stat. 1585 (1984).

company competitors in connection with the settlement of litigation arising under the Hatch-Waxman Act. The principal issue is whether a rule of reason analysis or a theory of *per se* illegality should govern the construction of such settlement terms.

In *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th 2003), *reh'g denied* (6th Cir. 2003), the Sixth Circuit held that such settlement payments were *per se* unlawful under the antitrust laws. In *Valley Drug. Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied*, (11th Cir. 2003), the Eleventh Circuit explicitly considered and rejected the Sixth Circuit's theory of *per se* illegality and held to the contrary that such provisions were presumptively lawful because they secured to the patentee no more than could have been obtained by enforcement of the patent in the settled litigation.

The far-reaching importance of this issue cannot be overstated. Many billions of dollars are at stake, and the current healthy pace of pharmaceutical innovation could be threatened if incentives to innovation are reduced. The NYIPLA respectfully submits that, as matters stand, infringement suits cannot be readily settled and its members and their clients are unable to interpret and apply the patent-antitrust precedents of this Court to avoid treble damages exposure. As representatives of intellectual property litigants, the NYIPLA believes that the issues faced by its members in counseling their clients who are considering the initiation or settlement of infringement actions must be resolved expeditiously.

It is respectfully requested that the Court grant leave to file the attached brief *amicus curiae* of the NYIPLA.

Respectfully submitted,

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

This brief is submitted on behalf of the New York Intellectual Property Law Association ("NYIPLA"), a professional association of more than 1,300 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property law.[1] NYIPLA members include in-house attorneys working for businesses that own, enforce and challenge patents as well as attorneys in private practice who represent both patent owners and accused infringers. NYIPLA members represent both plaintiffs and defendants in infringement litigation and also regularly participate in proceedings before the United States Patent and Trademark Office ("PTO"), including representation of parties to interferences, as well as representing applicants for patents.

A substantial percentage of NYIPLA members participate actively in patent litigation. Due in part to the concentration of a number of large pharmaceutical firms in the New York metropolitan area, smaller but still quite significant numbers of NYIPLA members participate regularly in litigation involving the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"),[2] as representatives of both segments of the pharmaceutical industry — the traditional research-based "branded" firms as well as their newer "generic" competitors.

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1. Pursuant to SUP. CT. R. 37.6, the NYIPLA and its counsel represent that they have authored this brief in whole, and that no person or entity other than the *amicus curiae* and its counsel have made a monetary contribution to the preparation or submission of this brief. Pursuant to SUP. CT. R. 37.2(b), a motion for leave is being filed concurrently herewith, since several parties have indicated that they are unable to consent to the filing of this brief.

2. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Both general patent litigators and Hatch-Waxman specialists must remain continuously apprised of the current antitrust ramifications of the initiation and settlement of patent litigation so that their clients can be counseled expeditiously, accurately and effectively. Additionally, to the extent settlements incorporate either patent licenses or refusals to license, the NYIPLA's members must remain conscious of developments regarding the controlling precedents of this Court as interpreted by the federal appellate courts in those related areas as well.

Since its founding in 1922, the NYIPLA has committed itself to maintaining the integrity of United States patent law, and to the proper application of that law. Nowhere is the rational and considered application of patent law principles more important to the economy of the United States than at the interface between those principles and the principles embodied in the antitrust laws.[3] Moreover, in no other industry are the economic stakes surrounding patent protection higher than in the pharmaceutical industry where the average total cost to develop a single new drug is now estimated at $802 million, where the members of the Pharmaceutical Research and Manufacturers of America invested over $30 billion in 2001 alone in discovering and developing new medicines, and where "Average total drug development time has gone from 8.1 years in 1960, to 11.6 years in the 1970s, to 14.2 years in the 1980s and 1990s".[4]

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3. If there were ever any doubt on that score, it would have been obviated by the testimony given during the lengthy hearings held in early 2002 under the joint sponsorship of the Antitrust Division of the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), the agencies charged with enforcement of the antitrust laws. FTC/DOJ, Public Hearings, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, (2002) (http://www.ftc.gov/opp/intellect/index.htm).

4. G.J. Glover, *Competition in the Pharmaceutical Marketplace*, at 1 and 3-4, Testimony before the FTC and the DOJ (March 19, 2002) (http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf).

To further the goal of a properly reasoned and evenly balanced application of both the patent and the antitrust laws, the NYIPLA urges this Court to grant certiorari to obviate an intolerable conflict between two United States courts of appeals under SUP. CT. R. 10(a),[5] and to announce authoritatively whether payments made to an accused patent infringer in connection with the settlement of an infringement action should be evaluated under the rule of reason (as the Eleventh Circuit held in *Valley Drug*), or proscribed as *per se* unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (as the Sixth Circuit held in *Cardizem*).

The NYIPLA takes no position at this time on whether the rule of reason should control or whether, to the contrary, the case should be treated under the standards set forth in this Court's previous articulations of the circumstances under which *per se* treatment of a restraint would be appropriate.[6] As Petitioners have pointed out (Pet. Br. at 25), it "has historically been the role and function of the Supreme Court" to promulgate guidelines for those situations in which the rule of reason should be abandoned in favor of a *per se* rule.[7]

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5. *Compare In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *reh'g denied* (6th Cir. 2003) ("*Cardizem*"), *with Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *reh'g denied* (11th Cir. 2003) ("*Valley Drug*"). For the convenience of the Court, references to the *Cardizem* and *Valley Drug* decisions herein are made by citation both to the official reporter and to Petitioners Appendix in the form "Pet. App. at __". References to Petitioners Brief herein are in the form "Pet. Br. at __".

6. *Northern Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958) (*per se* rule appropriate where challenged restraint lacks "any redeeming virtue"); *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999) (or "plausible procompetitive benefit").

7. *Citing Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 49-50 (1977).

Additionally, the NYIPLA respectfully submits that the Sixth Circuit's *Cardizem* decision would seem to raise issues under a number of this Court's previous decisions.[8] The NYIPLA makes no claim that the Sixth Circuit's *Cardizem* decision directly "conflicts with relevant decisions of this Court" under SUP. CT. R. 10(c).[9] However, if this Court should rule that "reverse" or "exit" settlement payments should be deemed *per se* unlawful, it would seem that some guidance regarding the continuing vitality of *PRE* and a number of this Court's other precedents regulating conduct at the antitrust-intellectual property interface also would be warranted.[10]

SUMMARY OF THE ARGUMENT

The nature of the stark conflict between the Sixth Circuit's *Cardizem* decision and the Eleventh Circuit's ruling in *Valley*

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8. *E.g., Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (setting forth the standards governing when the presumption of validity and good faith initiation of intellectual property litigation can be overcome) ("*PRE*"). Patent litigation practitioners have been advising their clients for almost ten years that the *PRE* standards are just as applicable to the settlement of patent litigation as to its initiation. Indeed, Judge Posner's recognition of this principle in *Asahi Glass Co. v. Pentech Pharm., Inc.*, __ F. Supp. 2d __, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003) ("*Asahi*"), represented a key theoretical underpinning for his criticism of the Sixth Circuit's *Cardizem* decision.

9. The NYIPLA nevertheless does believe that the Sixth Circuit's *Cardizem* decision "has decided an important question of federal law that has not been, but should be, settled by this Court" within the meaning of Rule 10(c).

10. As developed in Point I of the argument, the *Cardizem* decision calls into question no less than four separate touchstone principles, all derived from the decisions of this Court as interpreted by the United States courts of appeals, upon which counselors have come to rely in advising their clients on patent litigation settlements and related matters.

Drug is dealt with cogently and thoroughly in Point I of Petitioner's brief (Pet. Br. at 9-12),[11] and no further discussion of that conflict seems appropriate here.[12]

Point I

Point I of this brief discusses the confusion and potential for serious inconsistency faced by NYIPLA members as they struggle to counsel their clients while the conflict remains unresolved.[13] This focus on the practitioner's counseling role seems particularly appropriate in this field where representatives of both the DOJ and FTC enforcement agencies have repeatedly stressed the primary role of the private and corporate bars in securing and maintaining antitrust compliance.[14]

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11. In a recent article, two New York antitrust practitioners analogized this "notorious split" between the Sixth and Eleventh Circuits to "a storm" in "the antitrust world" and speculated that in order to "calm the fury", this Court might be prompted to examine whether settlement payments are "so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality". N.R. Stoll & S. Goldfein, *Patent Protection or Per Se Antitrust Violation?*, New York Law Journal, Nov. 18, 2003, at 3, *citing National Society of Professional Engineers v. United States*, 435 U.S. 679, 692 (1978).

12. The NYIPLA is mindful of this Court's directive that a brief for *amicus curiae* should be limited to "relevant matter not already brought to its attention by the parties" (SUP. CT. R. 37.1).

13. Point II of Petitioner's brief discusses the different but parallel confusion and potential for serious inconsistency in the lower federal courts absent the grant of certiorari and resolution of the conflict by this Court (Pet. Br. at 12-19).

14. *See, e.g.*, Thomas B. Leary, FTC, *The Dialogue Between Students of Business and Students of Antitrust: A Keynote Address*, Notre Dame Research Workshop and Conference on Marketing, Competitive Conduct and Antitrust Policy, at 4, (May 3, 2002) ("The people who (Cont'd)

Patent litigators and counselors have heretofore employed four separate touchstone principles in advising their clients on patent settlements and licenses: —

– First, because agreements settling patent litigation remain favored as a matter of public policy, the antitrust legality of their ancillary or subsidiary terms should be evaluated under the rule of reason rather than as naked horizontal restraints (Point I.A);

– Second, patent settlement agreements remain presumptively lawful unless and until proved to be "objectively baseless" under the standard announced by this Court in *PRE* (Point I.B);

– Third, because territorial and field of use market allocations represent lawful ancillary restraints in a patent license, a temporal restriction on entry can be justified *a fortiori* as representing nothing more than a promise not to infringe for all or a portion of a presumptively valid patent's remaining term (Point I.C); and

– Finally, a patentee's refusal to license is always justifiable as part of what the Solicitor General recently told this Court represented "the core patent right of exclusion" (Point I.D).

Each of the four touchstone principles is grounded in the prior decisions of this Court as interpreted by the federal

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really enforce the antitrust laws, day-to-day, are private counselors employed either as 'inside' or 'outside' lawyers."); William J. Kolasky, DOJ, *Antitrust Compliance Programs: The Government Perspective*, Before the Corporate Compliance 2002 Conference, Practising Law Institute (July 12, 2002).

appellate courts – for the last twenty years, perhaps most prominently by the Court of Appeals for the Federal Circuit.[15] In each of the four areas, the Sixth Circuit's *Cardizem* decision failed to indicate how a *per se* rule proscribing settlement payments could be accommodated with those precedents. Should the Court opt for a *per se* proscription of settlement payments, guidance will be required regarding the continuing vitality of the precedents upon which litigators at the interface have long been basing their advice.

Point II

The grant of certiorari here would facilitate essential guidance not only for the lower federal courts and for those who counsel the litigants therein, but also for the FTC. Two very recent developments highlight the prominent role that the FTC has assumed in evaluating the antitrust legality of patent settlement payments and suggest that timely guidance is warranted because this role may soon be greatly expanded.

First, on December 18, 2003, the FTC reversed the dismissal of a complaint by the Administrative Law Judge ("ALJ") and held both (a) that Complaint Counsel had discharged their initial burden of establishing that at least part of the payments made by a patentee to two ANDA filers under settlement agreements had been made in return for promises to defer generic entry to dates certain in advance of the expiration of the asserted patent, and (b) that the Respondent had failed to "demonstrate that the challenged

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15. Because of the Congressional mandate for uniformity in patent law which led to its creation, the regional federal courts of appeals have often deferred to the expertise of the Court of Appeals for the Federal Circuit in matters concerning the interface between patent law and antitrust.

provisions are justified by procompetitive benefits that are both cognizable and plausible".[16]

Second, on December 8, 2003, just ten days before the FTC issued its ruling in *Schering-Plough*, the President signed into law the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" ("Medicare Act"), the filing requirements of which make it virtually certain that the FTC staff will soon assume an even greater role in policing and challenging settlement payments.[17]

ARGUMENT

I. THE CONFLICT BETWEEN THE CIRCUITS RAISES SERIOUS PRACTICAL PROBLEMS FOR PATENT LITIGANTS WHO ARE CONSIDERING THE INITIATION OR SETTLEMENT OF INFRINGEMENT ACTIONS

A. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That Agreements Settling Patent Litigation Remain Favored As A Matter Of Public Policy

In the more than seventy years that have elapsed since the decision in *Gasoline Cracking*,[18] patent litigators have remained confident that this Court would continue to evaluate the terms of patent dispute settlements between potential competitors as

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16. *In re Schering-Plough*, Opinion of the Commission, at 8, FTC Docket No. 9297 (Dec. 18, 2003) ("*Schering-Plough*") (http://www.ftc.gov/os/adjpro/d9297/031218finalorder.pdf) (final order), (http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf) (opinion).

17. Pub. L. No. 108-173 (2003).

18. *Standard Oil Co. v. United States*, 283 U.S. 163 (1931).

ancillary or subsidiary terms under the rule of reason rather than as naked horizontal restraints. Frequent references in the decisions of this Court and the federal appellate courts to the strong public policy favoring the settlement of litigation in general and patent litigation in particular have buttressed this confidence. *E.g.*, *Callen v. Pennsylvania R.R. Co*, 332 U.S. 625, 630 (1948); *Asberry v. United States Postal Service*, 692 F.2d 1378 (Fed. Cir. 1982); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369-70 (Fed. Cir. 2001).

The public policy favoring the settlement of litigation so pervades the fabric of federal law that provisions of both the Federal Rules of Civil Procedure and the Federal Rules of Evidence have been tailored specifically to reflect that policy. *See Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1308 (Fed. Cir. 2001) (Fed. R. Evid. 408); *Marek v. Chesny*, 473 U.S. 1, 5 (1985) (Fed. R. Civ. P. 68).[19]

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19. In *Marek v. Chesny*, 473 U.S. at 5, this Court explained:

> The plain purpose of Rule 68 is to encourage settlement and avoid litigation. The Rule prompts both parties to a suit to evaluate the risks and costs of litigation, and to balance them against the likelihood of success upon trial on the merits.

(*citing Advisory Committee Note on Rules of Civil Procedure, Report of Proposed Amendments*, 5 F.R.D. 433, 483 n. 1 (1946), 28 U.S.C.App., p. 637). This Court went on to note that:

> Rule 68's policy of encouraging settlements is neutral, favoring neither plaintiffs nor defendants; it expresses a clear policy of favoring settlement of *all* lawsuits.

Id. at 10, (emphasis supplied). *See also*, *Evans v. Jeff D.*, 475 U.S. 717, 733 (1986) ("In approving the package offer in *Marek v. Chesny* we recognized that a rule prohibiting the comprehensive negotiation of all outstanding issues in a pending case might well preclude the settlement of a substantial number of cases: . . .").

The Court of Appeals for the Sixth Circuit cogently summarized the principle in *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1975), an opinion written by then Chief Judge Markey of the Court of Customs and Patent Appeals sitting by designation, where the Court said:

> Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter.

In *Cardizem*, however, the Sixth Circuit made no mention whatsoever of either the public policy favoring settlements, or its own prior decisions setting forth that principle. If public policy favors settlement agreements, their terms should be evaluated under a standard that encourages the parties to settle. Since application of the *per se* rule to settlement payments appears inconsistent with the public policy favoring settlement of patent litigation, clarification by this Court is required.

B. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume The Presumptive Legality Of Patent Settlements Which Are Not "Objectively Baseless" Under The *PRE* Standard

As mentioned in passing, *supra*, the Sixth Circuit's decision in *Cardizem* also failed to consider the effect of this Court's ruling in *PRE* that before initiation of an intellectual property lawsuit can be proscribed under the antitrust laws a two-part test must be satisfied:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits . . . Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation . . . This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

508 U.S. at 60-61 (emphasis in original).

Since initiation of a patent infringement action must be presumed legitimate unless and until proved to be "objectively baseless", settlement of such an action likewise must be presumed to represent a legitimate promise to forbear from further asserting valid patent claims against the accused infringer unless and until proved otherwise. Thus, even if a patent settlement results in the accused infringer remaining out of the marketplace until expiration of the patent, it must be presumed that the same result would have been achieved in the lawsuit by virtue of the presumptively valid patent.

Under the logic of *PRE*, therefore, it would seem that any challenge to a term of a settlement agreement would have to proceed under the rule of reason unless and until the challenger could demonstrate by objective evidence that legitimate entry would have occurred in spite of the patent — usually for reasons of invalidity or non-infringement.[20] The Sixth Circuit in *Cardizem* failed to consider whether a *per se* rule that assumes an anticompetitive effect would conflict with both the reasoning of *PRE* and the principle that patent claims must be presumed valid.[21]

C. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That The Legality Of Field-Of-Use, Territorial, And Other Conventional Patent License Terms In A Settlement Agreement Will Be Evaluated Under The Rule Of Reason

The enforcement agencies concede that intellectual property licensing "is generally procompetitive",[22] often "can facilitate

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20. There are, of course, situations where a settlement agreement could run afoul of the *PRE* standard without any formal showing of invalidity or non-infringement. For example, where the accused infringer becomes privy to clearly invalidating evidence, the *PRE* standard could be satisfied and the putative settlement agreement itself could be attacked under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. *See United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963). Additionally, the accused infringer could ascertain during discovery that the patent at issue had clearly been procured by fraud upon the PTO. Once again, the *PRE* standard could be satisfied by such a showing, and the "sham" settlement could be attacked under Sherman Act Sections 1and 2 under the authority of *Walker Process Equip., Inc. v. Food Mach. & Chem. Co.*, 382 U.S. 172 (1965).

21. 35 U.S.C. § 282.

22. FTC, *Antitrust Guidelines for the Licensing of Intellectual Property*, at 3 (Apr. 6, 1995), ("Licensing Guidelines") (http://www.usdoj.gov/atr/public/guidelines/ipguide.htm).

integration of the licensed property with complementary factors of production",[23] and in "the vast majority of cases" should be "evaluated under the rule of reason".[24] Thus, "Field-of-use, territorial, and other limitations on intellectual property licenses may serve procompetitive ends by allowing the licensor to exploit its property as efficiently and effectively as possible". Licensing Guidelines at 6. Proscription under a *per se* rule is reserved for those restraints which, under the decisions of this Court as interpreted by the federal courts of appeals: "merit *per se* treatment, including price fixing, allocation of markets or customers, agreements to reduce output, and certain group boycotts". *Id.* at 23.

The Sixth Circuit in *Cardizem* concluded that an agreement not to infringe a presumptively valid patent by entering the market before an agreed date could be characterized as a *per se* unlawful "horizontal agreement to eliminate competition in the market". *In re Cardizem*, 332 F.3d 896, 908 (6th Cir. 2003) (Pet. App. at 18a). It did so based upon a review limited to this Court's non-patent decisions explaining application of the *per se* rule (Pet. App. at 15a-17a). Moreover, the Sixth Circuit provided no rationale for distinguishing between, on the one hand, the proscribed temporal market allocation represented by the delayed entry of the generic and, on the other hand, the field of use and territorial market allocations which the FTC and DOJ have indicated are presumptively lawful.[25]

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23. *Id.* at 5.

24. *Id.* at 15.

25. Indeed, to the extent the Sixth Circuit in *Cardizem* may have equated "market allocation" with "naked horizontal restraints pertaining to . . . territories", it also ignored both 35 U.S.C. § 261 and the policy determinations of the DOJ and FTC as reflected in the Licensing Guidelines.

If this Court should determine that a *per se* analysis of settlement payments is appropriate, care should be taken that the announced rule does not extend to practices like territorial and field-of-use limitations which, unlike price fixing, the enforcement agencies agree should be assessed under the rule of reason.

D. Absent Resolution Of The Conflict Between The Circuits The Patent Community No Longer May Safely Assume That A Patentee May Refuse To License A Patent

In *Xerox (ISO)*, the Federal Circuit found "support" for the patentee's right to refuse to license with impunity in Congressional enactment of Section 271(d)(4) of the Patent Code.[26] The Federal Circuit concluded that, to the extent Section 271(d)(4) defines conduct that cannot support unenforceability, such a determination *a fortiori* should preclude any attempt to ground an antitrust violation upon the same conduct. While the Solicitor General's brief in this Court recommending against the grant of certiorari stopped short of directly endorsing that reasoning, the Solicitor General did concede that even the Ninth Circuit in *Kodak II* reads Section 271(d)(4) to "indicate congressional intent to protect the core patent right of exclusion" (Br. at 12 n.6).[27] The Federal Circuit also

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26. *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001). ("*Xerox (ISO)*").

27. *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1215 (9th Cir. 1996). Indeed, Congress included "market power" as a necessary element for removing a tying arrangement from the safe harbor of Section 271(d)(5) and failed to do the same for Section 271(d)(4). This suggests strongly that Congress intended refusals to license to remain permissible even where the exclusionary power of a patent claim can be shown to be coextensive with some economically significant relevant market.

extended the rule of *PRE* to the alleged Section 2 claim in *Xerox (ISO)*.[28]

The Sixth Circuit would have required only a slight extension of its logic in *Cardizem* to have held additionally that the "horizontal agreement to eliminate competition" was tantamount to a refusal to license during the period before delayed entry. To ameliorate the acute problems of interpretation that the patent community faces, should this Court determine that settlement payments should be tested under a *per se* rule, guidance should be provided as to whether the scope of that ruling extends as well to any aspect of 35 U.S.C. § 271(d).

II. THE GRANT OF CERTIORARI WOULD FACILITATE ESSENTIAL GUIDANCE ON SETTLEMENT PAYMENTS FOR THE FTC AS WELL

Although the FTC is not a party to the *Cardizem* action, its publication of an administrative FTC complaint prompted the actions later consolidated into the multidistrict proceeding in which the Sixth Circuit rendered its decision.[29] Moreover, the

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28. *In re Independent Serv. Orgs. Antitrust Litig.*, 203 F.3d at 1327-28. Irrespective of what particular constitutional provisions are deemed to support the *PRE* rule, it seems unfair to burden a jury with the task of differentiating between situations where a patentee's refusal to deal involves the presumptively legitimate purpose of "protection of intellectual property" and those where the purpose for the very same refusal is merely "pretextual". The Ninth Circuit's ruling in *Kodak II* clearly asked too much of the jury — particularly where it was necessary to find an erroneous instruction "harmless error" in order to sustain an $80 million verdict.

29. Indeed, this is a common pattern. In every instance where the FTC has challenged a settlement payment made in connection with the termination of an ANDA infringement action, purchaser classes and other treble damages plaintiffs subsequently have sought recovery under Section 4 of the Clayton Act, 15 U.S.C. § 15 — even where the

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FTC staff has often argued that ANDA settlement payments are *per se* illegal.[30]

Commissioner Leary's opinion in *Schering-Plough*, published on December 18, 2003, demonstrated full awareness of the conflict between the Sixth and Eleventh Circuits. While rejecting application of the *per se* rule of *Cardizem* and purporting to employ "a properly structured rule-of-reason inquiry" (Slip Op. at 87), the decision stopped well short of the full rule of reason inquiry used by the Eleventh Circuit in *Valley Drug*. Indeed, the FTC's order prohibits prospective settlements of ANDA litigation in which the generic "receives anything of value" other than payments "linked to litigation costs, up to $2 million, and for which the Commission has been notified of the settlement" (*Id.* at 88).

By prohibiting future settlement payments in excess of $2 million, the Commission has apparently signaled that it will no longer countenance payments in excess of that maximum even where such payments are commensurate with "expected litigation costs" as a recent consent settlement had permitted.[31] This seemingly arbitrary posture may represent the product of the Commission's apparent skepticism regarding the magnitude

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matter was promptly disposed of upon consent. *See Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), *complaint available at* (http:www.ftc.gov/os/2000/05/c3945complaint.htm); *Geneva Pharm., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), *complaint available at* (http://www.ftc.gov/os/2000/05/c3946complaint.htm); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), *complaint available at* (http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm).

30. *E.g.*, *In re Schering-Plough*, Opinion of the Commission, at 12, *citing* App. Br. at 70-71.

31. *Id.* at 37, citing *Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076, *available at* (http://www.ftc.gov/os/2003/03/bristolmyersdo.pdf).

of actual litigation costs.[32] Actual legal fees in patent litigation, however, sometimes can exceed $25 million.[33]

The Commission's order in *Schering-Plough* probably foreshadows the treatment that the industry can expect for ANDA settlement agreements under the Medicare Act amendment of December 8, 2003. Title XI, Subtitle B, Sec. 1112(c)(1) of that Act requires that each brand name and generic drug company entering into an ANDA agreement shall "file with the Assistant Attorney General and the Commission the text of any such agreement". Under Title IX, Sec. 903 of the "Drug Competition Act of 2003",[34] the purposes of the Act are (1) to provide timely notice to the DOJ and the FTC of agreements between companies who market patented proprietary drugs and generics and (2) to thereby enhance the enforcement of the antitrust and competition law of the United States.

Absent guidance from this Court, Hatch-Waxman litigants who wish to settle apparently will be faced with the choice of either settling on terms that the FTC will accept or risk FTC challenge to their settlements — with the daunting prospect of the private treble damages litigation under the Clayton Act, which inevitably follows any such challenge.

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32. *Id.* at 82, characterizing a payment of $5 million, although "ostensibly" for legal fees, as "probably well in excess of AHP's attorneys fees".

33. *See Bristol-Myers Squibb, Co. v. Rhone-Poulenc Rorer, Inc.*, 2002 WL 1733681 (S.D.N.Y. July 26, 2002), *aff'd*, 326 F.3d 1226 (Fed. Cir. 2003).

34. S. REP. NO. 108-1 (2003).

CONCLUSION

For all the foregoing reasons, the NYIPLA respectfully submits that this Court should grant certiorari to obviate an intolerable conflict between two United States courts of appeals and announce authoritatively whether payments made to an accused infringer in connection with the settlement of an infringement action should be evaluated under the rule of reason (as the Eleventh Circuit held in *Valley Drug*), or proscribed as *per se* unlawful under Section 1 of the Sherman Act (as the Sixth Circuit held in *Cardizem*). The expeditious resolution of this conflict is of critical importance for the entire patent community, because the potential ripple effect of *Cardizem* could affect application of any number of related principles upon which that community has long relied. Indeed, with the filing requirements of the Medicare Act now looming on the horizon, it is also of critical importance to the patent community that the FTC should obtain the authoritative guidance of this Court as well.

Respectfully submitted,

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No. 03-779

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IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

v.

THE KROGER CO., *ET AL.*

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Pursuant to Rule 37.2 of the Rules of this Court, the Pharmaceutical Research and Manufacturers of America (PhRMA) hereby moves for leave to file the accompanying brief as *amicus curiae* in support of petitioner. PhRMA's members invest billions of dollars each year to discover and develop new medicines, and are responsible for almost all of the innovative medicines that have been approved for use in the United States over the past several decades. As a result, PhRMA and its members have a large stake in intellectual property rights and the rules governing the resolution and settlement of patent disputes. Accordingly, they view the question presented by the petition in this case – whether certain patent settlements are subject to the *per se* rule under section 1 of the Sherman Act – as a matter of critical

importance. PhRMA participated in this action as *amicus curiae* in the court of appeals.

Petitioner has consented to the filing of the accompanying *amicus* brief; its counsel's written consent so stating has been submitted to the Clerk. Likewise, respondents Kroger Company, Albertson's, Inc., Hy-Vee, Inc., The Stop & Shop Supermarket Company, Walgreen Company, Eckerd Corporation, Aventis Pharmaceuticals, Inc. (formerly Hoechst Marion Roussel, Inc.), CVS Meridian, Inc., and Rite-Aid Corporation have consented, and their written consents have been submitted to the Clerk. Respondents Charles Zuccarini, Joseph D'Esposito, Shirlean Glover, Larry S. Sizemore, Albert Eirich, Aetna, Inc., and Cobalt Corporation have refused consent. Respondents Duane Reade, Inc., Louisiana Wholesale Drug Company, and Eugenia Wynne Sams have not responded to PhRMA's attempts to obtain their written consent.

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INTEREST OF THE *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's

[1] Pursuant to Rule 37.6, PhRMA states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/whoweare/members/. Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals Inc.), which was a defendant below and settled while the case was on appeal (*see* Pet. App. 14a n.9), is a member of PhRMA.

members invested more than $32 billion in 2002 to discover and develop new medicines. They are responsible for almost all of the innovative medicines that have been approved for use in the United States over the past several decades.

Intellectual property principles, including patent rights and the rules governing patent litigation and settlement, are of critical importance to PhRMA's members and to their research and development efforts. PhRMA participated in this case as an *amicus* in the court of appeals.

STATEMENT OF THE CASE

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires approval by the Food and Drug Administration (FDA) before a new drug may be marketed. *See* 21 U.S.C. § 355(a). A research-based company seeks initial approval by submitting a full new drug application (NDA), which contains extensive data from controlled clinical studies, animal tests, and laboratory investigations. *See* 21 U.S.C. § 355(b). A generic company may obtain approval of a copy of the innovator's drug by filing an abbreviated new drug application (ANDA), which contains much more limited information. *See* 21 U.S.C. § 355(j).

The FFDCA establishes complex procedures governing patent disputes between innovator and generic companies. *See* 21 U.S.C. § 355(j). These procedures are intended to allow the courts to resolve patent disputes before potentially infringing generic products enter the market. This is accomplished by staying FDA approval of the generic company's ANDA for 30 months while patent litigation is pending. The law also provides an incentive for generic companies to challenge patents in the form of 180 days of

exclusive ANDA marketing rights for the first company to submit such a challenge.[2]

This case arises out of patent litigation between an innovator company, Hoechst Marion Roussel, Inc. (HMR), and a generic company, petitioner Andrx Pharmaceuticals, Inc. (Andrx), which filed an ANDA for a copy of one of HMR's drugs, Cardizem® CD. When it appeared that the district court might not issue a decision before expiration of the 30-month stay, the parties entered into a stipulation rather than litigating a preliminary injunction motion that HMR was prepared to file. Pet. App. 97a. Under the stipulation, Andrx agreed to maintain the status quo while the litigation was pending, and HMR agreed to provide certain licensing rights and make certain payments to Andrx, among other things. The parties ultimately entered into a final settlement, pursuant to which Andrx agreed not to sell the original formulation of its product, and HMR agreed not to sue with respect to a noninfringing reformulation. When FDA approved the reformulated product, Andrx entered the market. Following an investigation, the Federal Trade Commission (FTC) determined that the stipulation did not delay market entry of a generic version of Cardizem CD by Andrx or any other manufacturer. *See* 66 Fed. Reg. 18636, 18638 (Apr. 10, 2001).

Respondents are plaintiffs in a number of class actions and individual cases alleging that the stipulation between Andrx and HMR violated the antitrust laws. These

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[2] Congress recently amended both the 30-month stay and 180-day exclusivity provisions of the law in sections 1101 and 1102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 1936 (2003). These changes do not affect the continued importance of the question presented by the petition in this case or the need for this Court's review.

cases were consolidated in the United States District Court for the Eastern District of Michigan. The district court ruled that the stipulation constituted a *per se* violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Pet. App. 34a-35a. On interlocutory appeal, the United States Court of Appeals for the Sixth Circuit affirmed. Pet. App. 1a, 4a.

SUMMARY OF THE ARGUMENT

The petition should be granted because it presents an important question on which there is a conflict between the circuits. Patent rights are the critical foundation for continued pharmaceutical innovation, and thus for the discovery and development of new medicines for patients with serious and life-threatening illnesses such as cancer and Alzheimer's disease. Patent disputes between innovator and generic companies are common and often involve "blockbuster" medicines used by millions of persons and with sales of billions of dollars. The rules governing settlement of these disputes are therefore critically important not only to the parties but to the entire healthcare sector. The Sixth Circuit erred by subjecting the settlement to the *per se* rule rather than undertaking a rule of reason analysis that would take into account the substantial procompetitive features of the stipulation at issue here. Its decision directly conflicts with a more recent decision of the Eleventh Circuit involving the same issues, *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310-11 (11th Cir. 2003). This Court should grant the petition to resolve the conflict.

ARGUMENT

Patent rights are absolutely vital to promoting pharmaceutical innovation.[3] Indeed, according to the FTC, innovation in the pharmaceutical industry "showcases the patent system's benefits" because it prevents low-cost free-riding by generics on the high upfront costs incurred by research-based companies to demonstrate safety and effectiveness as required for FDA approval of a full NDA.[4] Without effective patent and other intellectual property protections, industry could not make the substantial investments required to discover and develop new medicines.

While most generic drug applications seek approval only after the expiration of relevant patents, an increasing number in recent years include challenges to patents and request approval before patent expiration. An FTC study published in 2002 found that approximately 20 percent of ANDAs filed between 1998 and 2000 included patent challenges, a figure that had "increased substantially" over prior periods.[5] The drugs subject to patent challenges "represent some of the largest drug products as measured by annual sales, including [many] so-called 'blockbuster' drugs."[6]

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[3] *See, e.g.*, Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (2002) (at http://www.dallasfed.org/news/research/02science_grabowski.pdf).

[4] FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, at 14 (Oct. 2003) (at http://www.ftc.gov/os/2003/10/innovationrpt.pdf).

[5] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 10 (July 2002) (at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

[6] *Id.*

The stakes in these patent disputes are large: many of the drugs in issue have annual sales of more than $1 billion. Not surprisingly, the parties to pharmaceutical patent litigation frequently consider at least the possibility of settlement, and a number of cases have in fact been settled. Antitrust challenges to these settlements may arise in virtually any federal district court, and often challenges to the same settlement are filed in courts within the jurisdiction of different courts of appeals. It is therefore particularly important that the rules applicable to these settlements be well-established and uniform.

The Sixth Circuit erred in condemning a *bona fide* settlement of patent litigation as a *per se* violation of section 1 of the Sherman Act. This Court has long recognized that settlements of intellectual property disputes raise fundamentally different concerns from other types of agreements between competitors. *See, e.g., Standard Oil Co. (Indiana)* v. *United States*, 283 U.S. 163 (1931). The simple fact is that a presumptively valid patent operates to exclude others from the field of invention as claimed in the patent. A settlement of patent litigation involving a compromise of those rights in any respect will have procompetitive features that must be taken into account through a rule of reason analysis under section 1. Blanket condemnation under the *per se* rule ignores the economic and legal context in which these settlements arise, and it is inconsistent with this Court's antitrust jurisprudence. *See, e.g., California Dental Ass'n* v. *FTC*, 526 U.S. 756, 769-71 (1999); *Northwest Wholesale Stationers, Inc.* v. *Pacific Stationery & Printing Co.*, 472 U.S. 284, 296-98 (1985).

Shortly after the Sixth Circuit decided this case, the Eleventh Circuit reached the opposite result in a case raising precisely the same issue, *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d at 1310-11. The court in *Valley Drug* correctly rejected the *per* se approach, and observed that the exclusionary right granted by a patent must

be taken into account in evaluating the lawfulness of a settlement under section 1. *See id.* In view of the substantial and continuing importance of the issue, this Court should grant the petition to resolve the direct conflict between the circuits.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 2003

MOTION FILED
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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,
Petitioner,

v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC.,
THE STOP & SHOP SUPERMARKET CO., WALGREEN CO.,
ECKARD CORP., CVS MERIDIAN, INC.,
and RITE AID CORP., *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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On Petition for Writ of Certiorari
United States Court of Appeals
for the Sixth Circuit

MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioner. Petitioner has consented to the filing of this brief; its letter of consent has been lodged with the Clerk of the Court. WLF was unable to obtain the consent of Counsel for Respondents Charles Zuccarini, *et al.*, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. To that end, WLF has appeared in numerous federal and state courts in cases related to health care delivery. For example, WLF recently successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech relating to off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed,* 202 F.3d 331 (D.C.Cir. 2000). WLF also filed briefs in two cases that addressed issues virtually identical to the Question Presented in the Petition. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,* 344 F.3d 1294 (11th Cir. 2003); *In the Matter of Schering-Plough Corp.,* Docket No. 9297, 2003 FTC LEXIS 187 (F.T.C. Dec. 8, 2003).

WLF believes that both "innovator" and generic manufacturers play an important role in providing quality health care to the American public. If advances in health care are to continue, it is vital that innovator companies that develop new drugs and medical devices, or new methods of using those products, be afforded periods of patent protection, during which potential competitors are not permitted to market the same product. Patents provide an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new therapies will be able to realize a return on their investment when their research and development expenditures bear fruit. On the other hand, once an appropriate period of patent exclusivity has expired, consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

Competition between innovator and generic producers inevitably will lead to disagreements regarding precisely how long the legally-mandated exclusivity period for an innovator company's products should last. Those disagreements often will result in litigation, which usually is extremely time-consuming and expensive and diverts the attention of pharmaceutical executives away from finding ways to provide the public with innovative, low-cost pharmaceutical products. Accordingly, WLF believes that the law should provide strong incentives for parties to pharmaceutical patent litigation to settle their disagreements as quickly as possible.

WLF is concerned that the decision below provides precisely the wrong incentives. The Sixth Circuit appears to view litigation as just another forum within which innovator and generic companies can carry out their competition, and that litigation is to be encouraged as a means of ensuring that every potentially invalid patent is challenged in court. WLF is filing this brief because it strongly disagrees with that view. WLF believes that the settlement of litigation in most instances is pro-competitive. WLF also believes that the Sixth Circuit's position, by calling into question the legality of virtually all patent settlements, will actually discourage meritorious challenges by generic companies who are reluctant to undertake an expensive battle of indeterminate duration and outcome knowing that pre-trial settlement may not be an option.

WLF seeks to file this brief solely because of its interest in promoting the efficient settlement of patent disputes, including but not limited to, settlements between innovator and generic drug companies in the pharmaceutical industry. It has no direct interest, financial or otherwise, in the outcome of this case. Nor does it take a position on the merits of the underlying antitrust dispute.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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December 29, 2003

QUESTION PRESENTED

Whether an interim settlement of patent infringement litigation, in which the alleged infringer, for consideration, agrees to keep its product off the market until the claim of infringement is resolved, constitutes a *per se* violation of the Sherman Antitrust Act, irrespective of the validity of the claim of infringement or the reasonableness of the interim settlement.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

STATEMENT OF THE CASE

WLF hereby incorporates by reference the Statement of the Case contained in the Petition for a Writ of Certiorari.

In brief, this case is an antitrust challenge to a patent settlement agreement entered into between Petitioner Andrx Pharmaceuticals, Inc. and Hoescht Marion Roussel, Inc. (HMR). In 1996, HMR sued Andrx in federal district court in Florida, alleging that Andrx's plans to market a generic version of Cardizem CD (a drug initially developed by HMR) infringed various patents held by HMR.[2] The filing of the suit meant that FDA could approve Andrx's ANDA no earlier than

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

[2] In 1995, Andrx had submitted an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA), seeking permission from FDA to market a generic version of Cardizem CD. Under federal law, the mere filing of an ANDA (regardless whether any infringing product is ever manufactured, sold, or used) is deemed an act of infringement sufficient to trigger a patent holder's right to file a patent infringement suit. *See* Federal Food Drug and Cosmetic Act (FDCA) § 505(j), 21 U.S.C. § 355(j); *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

July 1998 -- 30 months after Andrx notified HMR of its intent to market a generic version of Cardizem CD. *See* 21 U.S.C. § 355(j)(5)(B)(iii). There is no dispute that the suit was vigorously contested by both sides.

FDA issued its final approval of Andrx's ANDA on July 9, 1998. Pursuant to the terms of the September 1997 Andrx/HMR interim settlement agreement (the "Stipulation"), Andrx began marketing its generic version of Cardizem CD in June 1999. That date was 11 months after Andrx received FDA approval of its ANDA, but many years before expiration of the patents that HMR alleged were being infringed by Andrx.

The Stipulation provided that Andrx would not begin marketing its product for so long as the patent infringement litigation was still pending and so long as no other generic versions of Cardizem CD were being marketed, regardless whether FDA approved its ANDA. Pet. App. 99a. In return, HMR agreed to pay Andrx $10 million per quarter year until the litigation was resolved. *Id.* at 100a-102a. If Andrx ultimately prevailed in the litigation, the Stipulation provided that HMR would pay Andrx $100 million for each year that the litigation lasted after the ANDA was approved (less credit for amounts previously paid). *Id.* If HMR prevailed, the Stipulation provided that Andrx could obtain a license from HMR to market its product.[3] Andrx and HMR entered into a final settlement of the patent litigation on June 9, 1999. HMR paid Andrx an additional $50.7 million at the time of the final

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[3] The Stipulation also required HMR to provide Andrx with certain information that would assist Andrx's marketing efforts, and prohibited HMR from seeking preliminary injunctive relief. *See id.* at 9a & n.6.

settlement, bringing to just under $90 million its total payments to Andrx.

The Andrx/HMR patent settlement agreement gave rise to a number of antitrust lawsuits filed by Respondents, drug purchasers who alleged that they were injured by the settlement. Those suits were eventually consolidated by the Judicial Panel on Multidistrict Litigation for pretrial proceedings in U.S. District Court for the Eastern District of Michigan. Respondents alleged that the Stipulation constituted an unreasonable restraint of trade, in violation of § 1 of the Sherman Act, 15 U.S.C. § 1, and various state antitrust laws. The district court thereafter granted Respondents' motion for partial summary judgment, ruling that the Stipulation was a horizontal restraint of trade that constituted a *per se* violation of antitrust law. Pet. App. 34a-82a.

The Sixth Circuit granted interlocutory appeal and subsequently affirmed. *Id.* 1a-33a. The appeals court said that the Stipulation was an agreement among competitors to allocate markets/limit production and that such horizontal output limitations "'are ordinarily condemned as a matter of law under an "illegal *per se*" approach because the probability that these practices are anticompetitive is so high.'" *Id.* at 17a (quoting *National Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 85, 100 (1984)). The court rejected arguments that a *per se* approach was inappropriate in the context of drug patent litigation settlements; the court said that the *per se* approach should apply to all horizontal market allocation agreements, regardless of the industry and regardless that the agreement arose in the context of a patent settlement. *Id.* at 19a. The appeals court deemed "irrelevant" Andrx's contention that the Stipulation lacked anticompetitive effects and had procompetitive benefits:

> To reiterate, the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case.

Id. at 20a.

REASONS FOR GRANTING THE PETITION

This case raises health care, patent, and antitrust issues of exceptional importance. By characterizing the Andrx/HMR patent litigation settlement agreement as a "market allocation agreement" subject to *per se* antitrust treatment, the Sixth Circuit has significantly degraded the value of intellectual property rights. The appeals court's ruling surely will make it far more difficult for drug patent holders to reach amicable settlements of disputes with potential infringers. Moreover, the ruling is likely to have ramifications far beyond drug patents; the appeals courts' reasoning includes any patent settlement where an alleged infringer agrees to cease infringing.

Patent protection for innovative drug products promotes further innovation by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new therapies will be able to realize a return on their investments when their research and development expenditures bear fruit. By undermining the value of that protection, the appeals court is undermining long-term health care in this country by reducing the financial incentives necessary to ensure that new, life-saving medical products continue to be developed.

As the Petition well demonstrates, the appeals court decision conflicts with decisions from numerous other federal courts, including the U.S. Court of Appeals for the Eleventh Circuit. The extent of that conflict increased just days after the Petition was filed, when a unanimous Federal Trade Commission issued an adjudicative decision rejecting the Sixth Circuit's *per se* approach. The FTC stated, "The current trend of authority seems to be moving in another direction," away from the Sixth Circuit's approach. *In the Matter of Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187 at *34-*35 (FTC Dec. 8, 2003). The FTC criticized the Sixth Circuit for failing to "take[] adequate account of Supreme Court decisions that mandate a more nuanced approach." *Id.* at *35 n.26.

WLF writes separately in order to emphasize just how far out of step the Sixth Circuit is with modern antitrust jurisprudence. This Court has condemned business practices as *per se* antitrust violations only in those instances in which courts consistently have found nearly identical practices in prior cases to have anticompetitive effects. Yet, the Sixth Circuit condemned the Andrx/HMR interim settlement as *per se* illegal without citing a single prior decision that determined similar patent litigation settlements to have anti-competitive effects. The Sixth Circuit deemed "irrelevant" Andrx's arguments that its settlement agreement and similar settlement agreements were procompetitive, indicating that *any* agreement by a potential patent infringer not to compete with the patent holder is *per se* illegal. Indeed, although the Sixth Circuit noted that Andrx received cash from HMR pursuant to the Stipulation, the court gave no indication that its ruling was limited to cases involving cash payments. Review is warranted to correct this major departure from established antitrust law which, if left uncorrected, will have significant negative impact both on intellectual property rights and on the delivery of health care.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW IS FAR OUT OF STEP WITH THIS COURT'S RECENT DECISIONS ON *PER SE* ANTITRUST ANALYSIS

This Court has made clear that *per se* treatment should be applied with great caution and only in the few cases where sufficient experience has shown that the conduct "always or almost always tend[s] to restrict competition and decrease output." *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985) (quoting *Broadcast Music, Inc. v. Columbia Broadcasting Sys.*, 441 U.S. 1, 19-20 (1979)). Indeed, only four years ago the Court warned that "the plausibility of competing claims about the effects of the [conduct at issue] rules out the indulgently abbreviated review." *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999).

The reason for this caution is clear. When the *per se* rule is applied to an agreement, a claimant need not prove: that a relevant market exists; that the accused parties have market power; that the accused parties' purpose is anticompetitive; or that the agreement has actual anticompetitive effects. Equally important, particularly in the context of these agreements, the defendant may not offer any explanation of the rationale for entering into the challenged agreement. The agreement is *presumed* to be illegal with limited inquiry into the exact type of harm caused. *Northwest Wholesale Stationers*, 472 U.S. at 289. Because the *per se* rule categorically condemns business arrangements, courts have explained that "a presumption exists that the circumstances of a case will be looked at in light of the rule of reason standard and will not be deemed per se

unreasonable." *All Care Nursing Serv., Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 746 (11th Cir. 1998).[4]

The *per se* rule should thus only be invoked when its application would generate a low risk of error – *i.e.*, to circumstances in which the courts have consistently found unambiguously anticompetitive conduct after applying the rule of reason to nearly identical conduct in prior cases:

> The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one. And of course what we see may vary over time, if rule-of-reason analyses in case after case reach identical conclusions.

California Dental, 526 U.S. at 780-81; *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 458 (1986) (refusing to force alleged conduct "into the 'boycott' pigeonhole" to resolve claim under *per se* rule).

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[4] Indeed, in recent years, the Court has specifically disapproved the application of *per se* rules in cases involving activity that in an earlier era might have been analyzed as *per se* unlawful. *See, e.g.*, *Broadcast Music*, 441 U.S. at 24 (blanket license agreement with price fixing effects not *per se* unlawful); *NCAA v. Board of Regents*, 468 U.S. 85, 103 (1984) (*per se* rule not applied to plan for televising college football games that included horizontal price fixing and output restrictions); *Northwest Wholesale Stationers*, 472 U.S. at 294 (appeals court's application of *per se* rule to concerted refusal to deal held inappropriate). Moreover, the Court has even reversed its own precedent in rejecting application of the rule to conduct previously considered to be *per se* unlawful. *See State Oil v. Kahn*, 522 U.S. 3, 7 (1997) (reversing Court's previous application of the *per se* rule to agreements to fix maximum resale prices).

The Sixth Circuit's application of the *per se* rule to the Andrx/HMR Stipulation is inconsistent with this well established "practice makes perfect" approach. It took this Court more than half a century of experience with group boycotts before the Court was willing to apply the *per se* rule to that type of conduct.[5] And since then, the Court has, on at least two occasions, further refined and narrowed its application of the *per se* rule in that context. *See Indiana Federation of Dentists*, 476 U.S. at 458-49; *Northwest Wholesale Stationers*, 472 U.S. at 294.

The Court's experiment with condemning vertical territorial restraints as *per se* illegal is similarly instructive of its caution. *Compare White Motor Co. v. United States*, 372 U.S. 253, 261-63 (1963) (reversing district court finding that vertical non-price restraints were illegal *per se* because "[w]e need to know more than we do about the actual impact of [vertical restraints] on competition to decide whether they ... should be classified as per se violations of the Sherman Act") *with United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 379 (1967) (applying *per se* treatment, noting that territorial "restraints are so obviously destructive of competition that their mere existence is enough") *and Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 48-50, 58-59 (1977) (describing *Schwinn* as "formalistic line drawing" and emphasizing that "[p]er se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive").

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[5] Arguably, the first significant boycott case heard by the Court was *W.W. Montague & Co. v. Lowry*, 193 U.S. 38 (1904). The Court did not formally declare group boycotts *per se* illegal under the Sherman Act until its decision in *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207 (1959).

The Sixth Circuit's application of the *per se* rule flies in the face of the experience of those courts that have actually assessed the competitive impact of patent litigation settlements. Before the appeals court's ruling, courts universally applied a rule of reason analytical framework to evaluate the legality of patent litigation settlements.[6] The only exception to this approach was where the agreements were found to mask an industry-wide price-fixing conspiracy.[7]

In rejecting the Sixth Circuit's approach, the Eleventh Circuit identified numerous potentially procompetitive effects of patent litigation settlement agreements, even agreements that involve cash payments from the patent holder to the alleged infringing party. For example, the Eleventh Circuit stated that *per se* antitrust analysis of patent litigation settlement agreements is inappropriate *even when the patent is later ruled invalid* because:

> Patent litigation is too complex and the results too uncertain for the parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This

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[6] *See, e.g., Standard Oil Co. (Indiana) v. United States,* 283 U.S. 163 (1931); *Hartford-Empire Co. v. United States,* 323 U.S. 386, 400, *clarified,* 324 U.S. 570 (1945); *Clorox Co. v. Sterling Winthrop, Inc.,* 117 F.3d 50 (2d Cir. 1997) (applying rule of reason in trademark case even though the settlement resembled a market allocation agreement).

[7] *See Noll v. O.M. Scott & Sons Co.,* 467 F.2d 295, 301 (6th Cir. 1972); *United States v. New Wrinkle,* 342 U.S. 371, 374 (1952); *see also Duplan Corp. v. Deering Milliken, Inc.,* 540 F.2d 1215, 1220 (4th Cir. 1976) ("it is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur").

> uncertainty, coupled with the treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.

Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).

Although it noted that HMR paid cash to Andrx in connection with the interim settlement, the Sixth Circuit did not limit its application of the *per se* rule to patent litigation settlements involving cash payments.[8] Under the Sixth Circuit's inflexible rule, *any* generic drug company that agrees not to market a product after receiving FDA approval of its ANDA violates § 1 of the Sherman Act. Moreover, there is no principled basis for limiting the Sixth Circuit's ruling to cases involving cash payments. As Judge Richard Posner has pointed out, in a decision criticizing the Sixth Circuit's *per se* approach:

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[8] The appeals court's decision appears to have been based in part on a misunderstanding of the hurdles a generic drug manufacturer must clear before bringing a product to market. A generic drug manufacturer may not market its product unless two conditions are met: (1) it has received marketing authority from FDA in the form of an approved ANDA; and (2) marketing will not violate a product monopoly granted by the federal government to another manufacturer, in the form of a patent. The Sixth Circuit apparently believed that only an approved ANDA was necessary. *See* Pet. App. 17a-18a (for "the price of $10 million per quarter" Andrx agreed to stay out of the market "even after it had obtained FDA approval"); *id.* at 2a (same). FDA does not, of course, pretend to grant generic drug companies authority to market products in violation of existing patents.

> [*A*]*ny* settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., ___ F. Supp. 2d ___, 2003 U.S. Dist. LEXIS 19370, at *21 (N.D. Ill. Oct. 29, 2003).

In sum, the Sixth Circuit's condemnation of patent litigation settlement agreements as *per se* antitrust violations not only conflicts directly with numerous other federal court decision but is far out of step with this Court's case law. Review is warranted to address those conflicts.

H. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW WILL DISCOURAGE LEGITIMATE SETTLEMENTS OF PATENT DISPUTES

Review is also warranted because the Sixth Circuit's decision, if left uncorrected, will have significant negative effects on intellectual property rights and on the development of new, life-saving therapies by the pharmaceutical industry.

In particular, largely for the reasons noted above, application of the *per se* rule in this case will have significant harmful consequences by discouraging patent settlements. The public policy favoring settlements is so well established that one author has deemed it a "truism." Stephen Bundy, *The Policy in Favor of Settlement in an Adversary System*, 44 HASTINGS L.J. 1, 48 (1992); *see, e.g.*, *Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("settlements rather than litigation will serve the interests of plaintiffs as well as defendants"); *Williams v.*

First Nat'l Bank, 216 U.S. 582, 592 (1910) ("compromises of disputed claims are favored by the courts").

These considerations are magnified in the patent context:

> Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld wherever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.

Aro Corp. v. Allied Witan Co., 532 F.2d 1368, 1372 (6th Cir. 1976) (citing *D.H. Overmeyer Co. v. Loflin*, 440 F.2d 1213 (5th Cir. 1971)). Indeed, studies show that patent litigation tends to be extraordinarily complex and expensive.[9] In addition, patent cases pose significant risks for both an intellectual property owner and an alleged infringer. An alleged infringer faces the potential of enormous damages

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[9] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 187-88 (1998) ("patent litigation tends to be exceptionally costly, with legal expenses often exceeding one million dollars per party"); Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. on Reg. 359, 380 (1999) ("Roughly $1 billion dollars is spent annually in the United States on patent litigation"); Tom Arnold, *Suggested Form of Contract to Arbitrate a Patent or Other Commercial Dispute*, 2 Tex. Intell. Prop. L.J. 205, 208 (Spring, 1994) (asserting that it takes "an average of more than six years for patent cases to make their way through the trial and appeal process").

awards,[10] while an intellectual property owner faces the possibility of its patents being found invalid or unenforceable.[11]

Contrary to the strong public policy favoring settlements, the Sixth Circuit's ruling discourages the orderly resolution of patent disputes. As suggested by FTC Commissioner Thomas B. Leary, application of *per se* treatment will "cast a cloud over all patent settlements"[12] so that patent owners and accused infringers will hesitate before entering into an agreement to resolve a patent dispute in fear that a court will deem their agreement to be *per se* unlawful. Much of this hesitation would flow naturally from the practical implications

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[10] *See, e.g.*, Carlson, *supra* note 9, at 380 ("[P]atent cases have produced some of the largest damages awards in history."); *Jury Finds Infringement of Plane Device Patent*, Nat'l L.J., Feb. 4, 2002, at C13 (verdict of nearly $47 million); John F. Manser, *Connolly Bove Lands $65 Million Verdict in IP Case: Trio Wins Fight Over Corn Gene in N.C. Trial*, Del. L. Wkly., Apr. 27, 1999, at 1 ($15 million in damages and $50 million in punitive damages); Kathleen Hollingsworth, *Federal Circuit: $72 Million in Damages in Hip Replacement Case Affirmed*, West's Legal News, Oct. 4, 1996, at 1996 WL 561184 ($72 million verdict).

[11] *See, e.g., Bet-the-Company Suit Leaves Chip-Maker Afloat*, Nat'l L.J., Feb. 4, 2002, at C29 (ethernet patent found invalid); *Shell Oil Prevails in Suit by Union Carbide*, Nat'l L.J., Jan. 21, 2002, at C7 (patents covering process of making ethylene oxides found invalid); *Genentech Defeats Huge Claim Over Cancer Drugs*, Jan. 21, 2002, at C7 (method and cell line patent claims found invalid); Margaret C. Fisk, *Company Loses $271 Million Claim Over Wireless Patents*, Del. L. Wkly., Jan. 8, 2002, at 4 (patents for infrastructure equipment used in cellular phone systems found invalid).

[12] Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes* at 9 (Nov. 3, 2000), *available at* www.ftc.gov/speeches/leary/learypharma.htm.

of the *per se* rule. Categorizing conduct as *per se* unlawful inevitably provides greater incentives for antitrust challenges. At least some of those challenges likely will be directed at conduct that, if analyzed under the rule of reason, would ultimately be found pro-competitive. In today's technology-based society,[13] where prompt, consensual conflict resolution is critical to continued innovation, any increased fear of settlement of patent disputes will have devastating consequences.

Nor can the Sixth Circuit's decision be ignored as an aberration that will have little impact elsewhere. Most pharmaceutical companies, including Andrx, sell their products nationwide. Any nationwide company that does business within the Sixth Circuit can be sued there and thus can be made subject to its rule. Unless the decision below is reversed, parties involved in drug patent litigation will be far more reluctant to enter into settlements, regardless where in the nation the drug patent litigation is pending.

The settlement-discouraging effects of the Sixth Circuit's approach are particularly disturbing because the antitrust laws are intended to encourage competition, yet the discouragement of patent litigation settlements is, in many instances, so clearly

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[13] There are approximately two million patents in force. *See* U.S. Patent & Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2000* (2001). The U.S. Patent & Trademark Office ("PTO") received nearly 300,000 patent applications in 2000, an increase of more than 12 percent over the previous year. *See* U.S. Patent & Trademark Office, *A New Organization for a New Millennium: Performance and Accountability Report (Fiscal Year 2000), available at* www.uspto.gov/web/offices/com/annual/2000. The PTO also issued a "record number" of patents in 2000. U.S. Patent & Trademark Office, *Patenting Trends Calendar Year 2000, available at* www.uspto.gov/web/offices/ac/ido/oeip/taf/pat_tr00.htm.

anticompetitive. As Judge Posner recognized, "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 2003 U.S. Dist. LEXIS at *21.

Moreover, a settlement that delays a generic company's entry into the market must be deemed procompetitive if, in the absence of a settlement, the patentee would likely have prevailed in the litigation and thereby obtained an injunction against any generic competition until long after the entry date permitted by the settlement. *Id.* Indeed, as the Petition notes, experience has shown that most generic companies are reluctant to market their product even after obtaining FDA approval of their ANDAs, for so long patent infringement litigation is still pending. The reason for that reluctance is not difficult to fathom. The advent of generic competition following expiration of a pharmaceutical patent generally leads to a sharp drop in a drug's price, and a corresponding drop in the innovator drug company's profits. If the generic competitor is found to have infringed an unexpired patent, its liability for repayment of all those lost profits would dwarf any profits it would have derived from selling the drug at a reduced price. Thus, because the threat of ruinous damage awards generally prevents the entry of generic competitors for so long as patent litigation continues, settlements (even ones providing for a delay of a generic company's market entry) are often procompetitive. Conversely, the Sixth Circuit's *per se* approach is anticompetitive because it discourages settlements.

Equally disturbing is the effect that the Sixth Circuit's *per se* approach is likely to have on innovation within the pharmaceutical industry. Any rule that decreases a patent holder's flexibility in negotiating with potential infringers

renders the patent less valuable. Pharmaceutical companies are less likely to maintain their multi-billion-dollar commitment to research and development of new products if they are afforded a decreased level of protection for the intellectual property that arises from those activities. The dramatic reduction in intellectual property rights threatened by the Sixth Circuit's decision is an issue of significant public concern. The Court should grant review to determine whether Congress really intended the antitrust laws to undermine the patent system in such a dramatic manner.

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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